

1822-CC11643

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IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS  
STATE OF MISSOURI

CURTIS L. MAHNKEN,

CAUSE NO. Pending

PLAINTIFF,

V.

WRIGHT MEDICAL TECHNOLOGY, INC.,  
MICROPORT ORTHOPEDICS, INC., and,  
PELLMED, LLC,

DEFENDANTS.

PETITION FOR DAMAGES

COMES NOW, Plaintiff, Curtis L. Mahnken, by and through counsel, Harper, Evans, Wade & Netemeyer, for his cause of action against Defendants, Wright Medical Technology, Inc., MicroPort Orthopedics, Inc., and PellMed, LLC, states as follows:

JURISDICTION AND VENUE

1. At relevant times hereto, Plaintiff, Curtis Mahnken, was and is a resident and citizen of the State of Missouri, residing 615 South Olive St., Mexico, Audrain County, Missouri 65265.
2. At all relevant times hereto Defendant Wright Medical Technology, Inc., is a foreign corporation doing business in the state of Missouri. Defendant may be served through its registered agent, CSC- Lawyers Incorporating Service Company at 221 Bolivar Street, Jefferson City, MO 65101.
3. Defendant Wright Medical Technology, Inc., at times relevant hereto, was engaged in the business of designing, manufacturing, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third-parties or related entities,

various prosthetic orthopedic products, including the Profemur<sup>®</sup> hip products that are in issue in this civil action.

4. MicroPort Orthopedics, Inc., is a foreign corporation with its principal place of business at 5677 Airline Road, Arlington, Tennessee, 38002. Defendant shall be served through its registered agent, CT Corporation System at 300 Montvue Rd. Knoxville, TN 37919.

5. Defendant MicroPort Orthopedics, Inc., at times relevant hereto, was engaged in the business of designing, manufacturing, distributing, selling, marketing and/or introducing into interstate commerce, either directly or indirectly through third-parties or related entities, various prosthetic orthopedic products, including some of the Profemur<sup>®</sup> hip products that are in issue in this civil action

6. Defendant PellMed, LLC, is a Missouri Limited Liability Corporation, doing business in the state of Missouri; Defendant may be served through its registered agent, Robin Dahle, at 8050 Watson Road, Suite 236, St. Louis, MO 63119.

7. MicroPort Orthopedics, Inc., at times relevant hereto, was responsible for conducting post-market surveillance, monitoring, reporting adverse events, and response to post-market surveillance issues, related to the Profemur<sup>®</sup> CoCr modular neck identified with the part number PHAC-1254.

8. Jurisdiction is proper in the state of Missouri pursuant to RSMO § 506.500.1(3), in that Defendants committed tortuous actions in the state of Missouri.

9. Venue is proper in the Circuit Court of the City of St. Louis, Missouri pursuant to RSMO § 508.010.4 in that Plaintiff was injured at Barnes-Jewish Hospital located at 1 Barnes Jewish Hospital Plaza, St. Louis, MO 63110.

10. Plaintiff, Curtis L. Mahnken, brings this action for his personal injuries and damages relating to the various Defendants' development, design testing, assembling, manufacture, packaging, labeling, marketing, distribution, supplying, and/or sale to him in the State of Missouri a defective artificial hip product known as a "Profemur" Hip System.

**STATEMENT OF FACTS**

11. On or about November 20, 2006, Plaintiff Curtis L. Mahnken had a Wright Medical artificial hip implanted in his right hip in a procedure known as a total hip arthroplasty (THA).

12. Paul S. Lux, M.D. was the orthopedic surgeon who implanted Plaintiff's Wright Medical artificial hip.

13. Plaintiff's November 20, 2006 hip implant surgery was performed at Barnes-Jewish West County Hospital in St. Louis, Missouri.

14. Paul S. Lux, M.D. did not violate any generally accepted standards of care in the field of orthopedic surgery in his care and treatment of Plaintiff in any of the following respects:

- a. In the care or treatment that he provided to the Plaintiff prior to beginning the hip implant surgery;
- b. In the information that he did or did not provide the Plaintiff prior to beginning the hip implant surgery;
- c. In the selection of the Wright Medical CoCr Profemur® modular neck, or any other Wright Medical artificial hip devices, that were implanted in the Plaintiff;
- d. In the hip implant surgery he performed on the Plaintiff;
- e. In the care or treatment that he provided to the Plaintiff, subsequent to Plaintiff's hip implant surgery; and,
- f. In the information that he did or did not provide to the Plaintiff subsequent to Plaintiff's hip implant surgery.

15. Based upon the patient population in which the Defendant Wright Medical intended its Profemur<sup>®</sup> artificial hip devices to be implanted, at the time of implantation with his Wright Medical Profemur<sup>®</sup> hip devices, Plaintiff Curtis L. Mahnken was an appropriate patient to be implanted with the Wright Medical Profemur<sup>®</sup> hip devices he received.

16. Paul S. Lux, M.D. recommended the Wright Medical Profemur<sup>®</sup> hip devices to Plaintiff and indicated that the Wright Medical Profemur<sup>®</sup> hip devices were appropriate for him.

17. Curtis L. Mahnken reasonably relied upon Paul S. Lux, M.D. in deciding to proceed with hip replacement surgery and have Wright Medical Profemur<sup>®</sup> hip devices implanted in him.

18. "Patient Testimonials" and "Patient Stories" published by Defendant Wright Medical in print and on various Wright Medical's internet website pages prior to November 20, 2006, promoting Wright Medical's hip products, illustrate and demonstrate the patient population, and activity levels, that Wright Medical intended and expected for its Profemur<sup>®</sup> and Conserve<sup>®</sup> hip devices.

19. Before the Plaintiff's November 20, 2006 surgery, Defendant Wright Medical supplied the Wright Profemur<sup>®</sup> and Conserve<sup>®</sup> hip devices that were implanted in Plaintiff to Barnes-Jewish West County Hospital in St. Louis, Missouri.

20. In his total hip replacement surgery on November 20, 2006, Plaintiff Curtis L. Mahnken had implanted in his right hip the following specific Wright Medical artificial hip devices:

- a. Conserve<sup>®</sup> Plus Cup  
Ref: 3802-5460; Lot: 076354493  
Shell Size 60mm O.D; I.D. 54 mm  
Material: CoCr; Surface Beaded
- b. Conserve<sup>®</sup> Total A-Class<sup>™</sup> Femoral Head  
REF: 38AM-5400; Lot: 106377461  
W/BFH<sup>®</sup> Tech.; Medium Neck

54mm OD; Neck Medium

- c. Profemur® LX Stem  
Ref: PRLX-0013; Lot: 096351936  
Medial Lgth 140; Lateral Lgth 160  
Surface Plasma Material: Ti6Al4V
- d. Profemur® Modular Neck  
Ref: PHA0-1254; Lot #: 076363502  
Size: 8DG; Var/Val Long  
Material: Ti6Al4V

21. Based upon the intended patient population that Wright Medical expected their Profemur® and Conserve® hip devices to be implanted in, and when Plaintiff Curtis L. Mahnken had these devices implanted in him, he was an appropriate patient to be implanted with these Wright Medical Profemur® and Conserve® hip devices.

22. Subsequent to the date of implantation of his Wright Medical artificial hip, Plaintiff used his Wright Medical artificial hip in a normal and reasonably expected manner.

23. Subsequent to the date of implantation of his Wright Medical artificial hip, Plaintiff used his Wright Medical artificial hip in a manner consistent with what was expected in the patient population these devices were intended for.

24. Subsequent to the date of implantation of his Wright Medical artificial hip, Plaintiff used his Wright Medical artificial hip in a manner consistent with many of the representations made in "Patient Testimonials" and "Patient Stories" that appeared in the Wright Medical websites.

25. After initial recovery from his November 20, 2006 surgery, for a period of time Plaintiff's Wright Medical artificial hip performed as expected, and the pain and disability Plaintiff had experienced in his right hip prior to his November 20, 2006 surgery had been substantially relieved.

26. On or about the date of March 16, 2015, approximately eight years and four months after his November 20, 2006 implant surgery, Plaintiff Curtis L. Mahnken, sustained a fracture of the Profemur modular neck component of his Wright Medical artificial hip.

27. The fracture of the modular neck component of the Plaintiff's Wright Medical hip occurred in when he was sitting at his home in Mexico, Missouri.

28. On March 18, 2015, emergency surgery, known as a "revision" surgery, was performed at Barnes-Jewish Hospital in City of St. Louis, St. Louis County, Missouri, by orthopedic surgeon Cara Alessandra Cipriano, M.D., to remove and replace the failed and damaged components of Plaintiff's Wright Medical artificial hip.

29. With the exception of the fact that the titanium Profemur Modular Neck component of Plaintiff's artificial hip had fractured, at the time of his revision surgery on March 18, 2015, Plaintiff was not otherwise in need of hip revision surgery.

30. With the exception of the fact that the titanium Profemur Modular Neck component of Plaintiff's artificial hip had fractured, at the time of Plaintiff's March 18, 2015 revision surgery each of the devices of the Plaintiff's Wright Medical hip was in substantially the same condition in all relevant respects as when they had left the control of Defendant Wright Medical.

31. Upon information and belief, prior to performing plaintiff's March 18, 2015 revision surgery, plaintiff's surgeon, Dr. Cipriano, contacted and consulted with Chuck Pellegrino, who had formerly been a Wright Medical sales representative of Profemur® and Conserve® hip devices in the St. Louis area.

32. Upon information and belief, on March 18, 2015 defendant PellMed, LLC., was the St. Louis area distributor of Profemur® and Conserve® hip devices.

33. Upon information and belief, on March 18, 2015 Chuck Pellegrino, was the owner, and an officer and employee, of defendant PellMed, LLC.

34. Upon information and belief, prior to performing plaintiff's March 18, 2015 revision surgery, plaintiff's surgeon, Dr. Cipriano, contacted and consulted with Jamie Sease, a former Wright Medical Product Development Engineer.

35. Upon information and belief, on March 18, 2015 Jamie Sease was at that time the Field Marketing Manager of Defendant MicroPort Orthopedics, Inc.

36. Upon information and belief, Jamie Sease, in her capacity as an employee of Defendant MicroPort Orthopedics, Inc., was present at the Plaintiff's March 18, 2015 revision surgery.

37. Upon information and belief, Chuck Pellegrino, in his capacity as an employee of Defendant PellMed, LLC, and as a sales representative for Profemur<sup>®</sup> hip products, was present at the Plaintiff's March 18, 2015 revision surgery.

38. Plaintiff Curtis L. Mahnken's March 18, 2015 revision surgery included:

- a. Removal of the Wright Medical Conserve<sup>®</sup> Femoral head with the imbedded fractured proximal portion of the Wright Medical titanium Profemur<sup>®</sup> Modular neck;
- b. The removal of the fractured distal portion of the titanium Profemur<sup>®</sup> modular neck from the otherwise well-fixed femoral component, the Profemur<sup>®</sup> TL Stem;
- c. Inserting a MicroPort CoCr Profemur<sup>®</sup> Plus Modular neck into the previously implanted Profemur<sup>®</sup> TL Stem;
- d. Placing a MicroPort Conserve<sup>®</sup> Femoral head onto the newly implanted MicroPort CoCr Profemur<sup>®</sup> Plus Modular neck.

39. The new devices implanted in Plaintiff Curtis L. Mahnken's right hip in his March 18, 2015 revision surgery included:

- a. Conserve® A-Class™ Femoral Head; W/BFH® Tech.  
REF: 38AM5435; Lot: 128752861  
54mm OD; Neck Long
- b. Profemur® Plus Modular Neck  
REF: PHAC-1254; Lot: 1543399  
Size: Long 8 DG Var/Val

40. The Conserve® and Profemur® hip devices described immediately above and implanted in Plaintiff in his revision surgery on March 18, 2015, were designed and manufactured by Defendant Wright Medical Technology, Inc.

41. The Conserve® and Profemur® hip devices described above and implanted in Plaintiff in his revision surgery on March 18, 2015, were sold by Defendant MicroPort to Defendant Barnes-Jewish Hospital for use in surgery performed on the Plaintiff at its hospital in the City of St. Louis.

42. The Conserve® and Profemur® hip devices described above and implanted in Plaintiff in his revision surgery on March 18, 2015, were distributed by Defendant PellMed, LLC, to Defendant Barnes-Jewish Hospital for use in surgery performed on the Plaintiff at its hospital in the City of St. Louis.

43. Based upon the intended patient population that Wright Medical and MicroPort expected the Profemur® and Conserve® hip devices to be implanted in, and when Plaintiff Curtis L. Mahnken had these devices implanted in him on March 18, 2015, he was an appropriate patient to be implanted with these Wright Medical Profemur® and Conserve® hip devices.

44. Orthopedic surgeon Cara Alessandra Cipriano, M.D., did not violate any generally accepted standards of care in the field of orthopedic surgery in her care and treatment of the Plaintiff in any of the following respects:

- a. In the care or treatment that she provided to the Plaintiff prior to beginning the hip revision surgery;

- b. In the information that she did or did not provide the Plaintiff prior to beginning the hip revision surgery;
- c. In the selection of the Wright Medical CoCr Profemur<sup>®</sup> modular neck, or any other Wright Medical artificial hip devices, that were implanted in the Plaintiff;
- d. In the decision to remove any of the Wright Medical hip devices that were removed in the hip revision surgery;
- e. In the decision not to remove the Wright Medical hip devices that were not removed in the hip revision surgery
- f. In the hip revision surgery she performed on the Plaintiff;
- g. In the care or treatment that she provided to the Plaintiff, subsequent to Plaintiff's hip revision surgery; and,
- h. In the information that she did or did not provide to the Plaintiff subsequent to Plaintiff's hip implant surgery.

45. Subsequent to March 18, 2015, Plaintiff used his revised hip and its Profemur<sup>®</sup> and Conserve<sup>®</sup> hip devices in a normal and reasonably expected manner.

46. Subsequent to the March 18, 2015 implantation of his Profemur<sup>®</sup> and Conserve<sup>®</sup> hip devices, Plaintiff used his revised hip and its Profemur<sup>®</sup> and Conserve<sup>®</sup> hip devices in a manner consistent with what was expected in the patient population these devices were intended for.

47. Subsequent to the March 18, 2015 implantation of his Profemur<sup>®</sup> and Conserve<sup>®</sup> hip devices, Plaintiff used his revised hip and its Profemur<sup>®</sup> and Conserve<sup>®</sup> hip devices in a manner consistent with many of the representations made in "Patient Testimonials" and "Patient Stories" that previously had appeared in the Wright Medical websites that existed at various times since his original total hip arthroplasty in 2006.

48. After initial recovery from his March 18, 2015 revision hip surgery, for a period of time Plaintiff's revised artificial hip performed as expected, and he had substantially recovered

from the pain and disability he had experienced in his right hip at the time of the modular neck fracture on March 16, 2015, and the trauma of the revision surgery.

49. On or about the date of January 27, 2018, approximately two years and ten months after his March 18, 2015, revision surgery, Plaintiff Curtis L. Mahnken, sustained a fracture of the Profemur® Plus CoCr Modular Neck component of his artificial hip.

50. The fracture of the Profemur® Plus CoCr Modular Neck component of the Plaintiff's Wright Medical hip occurred while walking up stairs in his home in Mexico, Missouri.

51. On January 29, 2018, a second emergency revision hip surgery was performed at University Hospital in Columbia Missouri, by orthopedic surgeon James A. Keeney, M.D., to remove and replace the failed and damaged components of the Plaintiff's artificial hip.

52. With the exception of the fact that the titanium Profemur® Plus CoCr Modular Neck component of Plaintiff's artificial hip had fractured and caused injury to the Plaintiff, at the time of his revision on January 29, 2018, the Plaintiff was not otherwise in need of hip revision surgery.

53. With the exception of the fact that the Profemur® Plus CoCr Modular Neck component of Plaintiff's artificial hip had fractured, at the time of Plaintiff's January 29, 2018 revision surgery each of the devices of the Plaintiff's artificial hip was in substantially the same condition in all relevant respects as when they had left the control of Defendants Wright Medical and MicroPort.

54. Plaintiff Curtis L. Mahnken's January 29, 2018 revision surgery included:

- a. Performing an extended trochanteric osteotomy to remove the otherwise well-fix Wright Medical Profemur® LX stem and the imbedded fractured distal remnant of the Profemur® Plus CoCr Modular Neck;
- b. Removal of the Conserve® Femoral head with the imbedded fractured proximal portion of the Profemur® Plus CoCr Modular Neck;
- c. The removal of the Conserve® Plus acetabular cup system;

- d. Femoral reconstruction to repair the damage done to the Plaintiff's femur in performing the extended trochanteric osteotomy, including the use of wire cables to hold the femoral bone fragments in place; and,
- e. Reconstruction of the Plaintiff's artificial right hip with screws and hip devices provided by medical device manufacturers other than Wright Medical or MicroPort.

55. Dr. Keeney, M.D., did not violate any generally accepted standards of care in the field of orthopedic surgery in his care and treatment of the Plaintiff in any of the following respects:

- a. In the care or treatment that he provided to the Plaintiff prior to beginning the hip revision surgery;
- b. In the information that he did or did not provide the Plaintiff prior to beginning the hip revision surgery;
- c. In the decision to remove all of the Wright Medical and MicroPort hip devices that were removed in the hip revision surgery;
- d. In the hip revision surgery he performed on the Plaintiff;
- e. In the care or treatment that he provided to the Plaintiff, subsequent to Plaintiff's hip revision surgery; and,
- f. In the information that he did or did not provide to the Plaintiff subsequent to Plaintiff's hip implant surgery.

#### **ACCRUAL OF PLAINTIFF'S CAUSES OF ACTION**

56. Prior to March 16, 2015, Plaintiff had neither knowledge nor notice that there was any defect in the design, manufacture or labeling of his implanted titanium Profemur® Modular Neck.

57. Prior to January 27, 2017, Plaintiff had neither knowledge nor notice that there was any defect in the design, manufacture or labeling of his implanted Profemur® Plus CoCr Modular Neck.

58. Earliest in time of the Plaintiff's causes of action alleged in this Complaint did not accrue until March 16, 2015.

**WRIGHT MEDICAL, MICROPORT, and the PROFEMUR® HIP**

59. In approximately the year 1985 a European manufacturer of artificial hip devices, known as Cremascoli Ortho Group ("Cremascoli"), developed the first prototype of what became known as the titanium Profemur® Modular Necks.

60. The first prototype of what became known as the titanium Profemur® Modular Necks were patented with the European Patent Office by Cremascoli in 1986.

61. What became known as the titanium Profemur® Modular Necks were first distributed in Europe by Cremascoli in 1986.

62. The name PROFEMUR® was originated by Cremascoli as a brand name for certain models or designs of its artificial hip devices.

63. Cremascoli Profemur® prosthetic hip devices are the subject of medical literature published in 1996. [See: The Modular Prosthesis for Hip Revision Surgery: Experience with the Profemur Stem: Masse, Scagnelli, Trossarello, Buratti, Randelli, Basso, Dei Poli, Giaretta, Leonardi, Massetti, Pugliese: Italian Journal of Orthopaedics and Traumatology-Suppl. 1, Vol XXII. - Fasc. 2- GIUGNO 1996.]

64. The above referenced 1996 medical literature is cited by Wright Medical in various Wright Medical Profemur® Technical Monographs that it created and distributed. [e.g., PROFEMUR™ TOTAL HIP SYSTEM, PERFORMANCE CHARACTERISTICS OF THE PROFEMUR™ TOTAL HIP SYSTEM, ©2002 Wright Medical Technology, Inc., MH688-102; and, PROFEMUR® R Revision Hip System, TECHNICAL MONOGRAPH, ©2010 Wright Medical Technology, MH688-102, Rev. 6.10, among others.]

65. In December 1999, Wright Medical Group, Inc., the parent corporation of Wright Medical Technology, Inc., purchased Cremascoli Ortho, acquiring Cremascoli's Profemur<sup>®</sup> artificial hip product line, related documents, and manufacturing facilities in Toulon France.

66. Based on publicly available patent documents of Cremascoli, it appears that there was a change in some aspects of the design of the titanium Profemur<sup>®</sup> modular necks before these products were first distributed in the United States. [Hereinafter at times referred to as a "re-design".]

67. Upon information and belief, before the acquisition of Cremascoli by Wright Medical, a re-design of the Profemur<sup>®</sup> Modular Necks at the mid-body of the neck increased the range of motion of the hip joint in an assembled artificial hip when used with compatible femoral heads and acetabular components. [Hereinafter these re-designed Profemur<sup>®</sup> Modular Necks at times are referred to as the "PHA0" modular necks.]

68. "Version" is the term Wright Medical used for the different lengths and angles of its Profemur<sup>®</sup> Modular Necks, identified by unique catalog numbers. For example, the Wright Medical Profemur<sup>®</sup> titanium varus/valgus 8° long neck, catalog # PHA0-1254, was one "version" of a Wright Medical Profemur<sup>®</sup> Modular Neck.

69. By the end of the year 1998, the Cremascoli modular neck product line had been expanded to include "versions" of modular necks that did not exist in 1986.

70. After the acquisition of Cremascoli, Wright Medical expanded the Profemur<sup>®</sup> product line to include additional designs and "versions" of Profemur<sup>®</sup> Modular Necks that did not exist prior to its acquisition of Cremascoli.

71. Sometime after the acquisition of Cremascoli, Wright Medical began to refer to some of its products as the "Profemur<sup>®</sup> Total Hip System."

72. On September 26, 2000, Wright Medical Technology, Inc. notified the United States Food and Drug Administration [FDA] of its intent to market what it called the “PRO-FEMUR R Revision Hip System” by way of what is known as an Abbreviated 510(k) Premarket Notification. [See: FDA 510(k) K003016.]

73. Wright Medical’s Abbreviated 510(k) Premarket Notification for the PRO-FEMUR R Revision Hip System Device Description included, “twelve modular necks which are available in six versions and two lengths: Neutral, anteversion/retroversion 8° or 15°, varus/valgus 8°, or combination of anteverted/retroverted – varus/valgus (in both short and long lengths).”

74. On December 13, 2000, Wright Medical Technology, Inc. received clearance from the FDA to market the PRO-FEMUR R Revision Hip System in the United States.

75. The FDA itself did not test in a laboratory the safety or efficacy of the Profemur® R Revision Hip System stem, nor the accompanying titanium Profemur® modular necks, as a part of the Abbreviated 510(k) process.

76. Sometime after December 13, 2000, Defendant Wright Medical Technology, Inc., began to manufacture, label, market, promote, distribute and sell in the United States the Wright Medical Profemur® Total Hip System and its components.

77. Sometime after December 13, 2000, Defendant Wright Medical Technology, Inc., began to manufacture, label, market, promote, distribute and sell in the United States Wright Medical titanium Profemur® Modular Necks.

78. On March 11, 2002, Wright Medical Technology, Inc. filed an application with the United States Patent and Trademark Office to register the trademark “PROFEMUR” in the United States. [See: U.S. Trademark Registration Number: 76380670.]

79. After receiving the 510(k) clearance to market the PRO-FEMUR® R Revision Hip System, over time Wright Medical expanded the Profemur® prosthetic hip stem product line to include additional designs of Profemur® Stems, including hip stems branded with names such as the Profemur® Z Hip Stem, Profemur® Plasma Z Hip Stem, Profemur® LX Hip Stem, and the Profemur® TL Hip Stem, among others.

80. Sometime after January 13, 2000, Defendant Wright Medical began to describe its Profemur® hip devices to its distributors, sales representatives, and surgeons, in printed brochures that it created, copywrote, and distributed, known as "Technical Monographs."

81. Sometime after January 13, 2000, Defendant Wright Medical began to describe its Profemur® hip devices to its distributors, sales representatives, and surgeons, on and through internet website pages that it created, copywrote, and controlled.

82. Sometime after January 13, 2000, Defendant Wright Medical began to promote and market its Profemur® hip devices to the general public, on and through internet website pages that it created, copywrote, and controlled.

83. In various Technical Monographs material created, copywritten, and distributed by Wright Medical beginning in approximately the year 2002, and continuing into the year 2005, Wright Medical made the following representations, statements, and claims about its Profemur® modular necks:

The modular neck used with the Profemur® Hip has been employed by Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur® Hip. None of the necks has experienced a clinical failure since their inception.

[e.g., Wright Medical Technical Monograph MH688-102 ©2002, and © 2004.]

84. Wright Medical knew that the above quoted statement by Wright Medical that, "None of the necks has experienced a clinical failure since their inception," was false when first made.

85. Prior to December 1, 2008, Wright Medical never corrected or recanted the above quoted statement by Wright Medical, "None of the necks has experienced a clinical failure since their inception."

86. In various Technical Monographs created, copywritten, and distributed by Wright Medical beginning in approximately the year 2002, and continuing into the year 2005, Wright Medical made the following representations, statements, and claims about its Profemur® modular necks:

The modular neck system, designed by Cremascoli in 1985 (U.S. Patent # 4,957,510), has now been successfully implanted in over 50,000 patients requiring both primary and revision hip arthroplasty. Extensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees:

- Structural reliability
- Absence of significant micromovement
- Absence of fretting corrosion

[e.g., Wright Medical Technical Monograph MH688-102 ©2002, and © 2004.]

87. The above quoted statement by Wright Medical that it, "guaranteed . . . absence of fretting corrosion," with its Profemur® modular necks was false at the time it was first made.

88. Wright Medical has never corrected or recanted the above quoted statement that it, "guaranteed . . . absence of fretting corrosion," with its Profemur® modular necks.

89. In various marketing and informational material published and distributed by Wright Medical, and available to Wright Medical's sales representatives and distributors, surgeons, patients and the general public, Wright Medical made representations, statements, and

claims about its Conserve<sup>®</sup> and Profemur<sup>®</sup> hip product lines that these products were intended for patients who wanted to return to an “active lifestyle.”

90. In various marketing and informational material published and distributed by Wright Medical, and available to Wright Medical’s sales representatives and distributors, surgeons, patients and the general public, Wright Medical made representations, statements, and claims about its Conserve<sup>®</sup> and Profemur<sup>®</sup> hip product lines that these products were intended for patients who wanted to return to and engage in various sporting, athletic, and lifestyle activities, such as golf, tennis, running, dirt bike racing, wrestling, active military duty, karate, and heavy labor.

91. In various marketing and informational material published and distributed by Wright Medical, and available to Wright Medical’s sales representatives and distributors, surgeons, patients and the general public, Wright Medical made representations, statements, and claims about its Conserve<sup>®</sup> and Profemur<sup>®</sup> hip product lines that these products had been implanted in patients who had returned to or engaged in various sporting, athletic, and lifestyle activities, such as golf, tennis, running, dirt bike racing, wrestling, active military duty, karate, and heavy labor.

92. In various marketing and informational material published and distributed by Wright Medical, and available to Wright Medical’s sales representatives and distributors, surgeons, patients and the general public, Wright Medical made representations, statements, and claims about its Conserve<sup>®</sup> and Profemur<sup>®</sup> hip product lines that these products were expected to last 10 to 15 years.

93. In marketing its Conserve® and Profemur® hip product lines to surgeons, one or more Wright Medical sales representatives made representations to one or more surgeons that Wright Medical Conserve® and Profemur® hip products were expected to last at least 20 years.

94. Modular necks which Wright Medical represented in literature it created and distributed in the United States, © 2002 and © 2004, for its marketing of these devices as having been “designed by Cremascoli in 1985,” and “successfully implanted in over 50,000 patients,” included the original modular neck design that existed prior to the re-designed [PHA0] necks.

95. Prior to the year 2000, Cremascoli had received notice of clinical failures in the form of fractures of its modular necks that had been “designed by Cremascoli in 1985.”

96. Prior to the year 2000, Wright Medical had received notice of clinical failures in the form of fractures in Europe of the modular necks that had been “designed by Cremascoli in 1985.”

97. Once Wright Medical filed a 510(k) Premarket Notification application to distribute its Profemur® modular necks in the United States, Wright Medical had a duty to report to the FDA any, each, and all events it received notice of where it was claimed that there had been a fracture in a patient of a Profemur® modular neck.

98. Once Wright Medical received clearance to distribute titanium Profemur® modular necks in the United States as a result of its 510(k) Premarket Notification application, Wright Medical had a duty to report to the FDA any, each, and all events it received notice of where it was claimed that there had been a fracture in a patient of a Profemur® modular neck.

99. Prior to January of 2005, Wright Medical knew of or received notice of fractures in patients of Profemur® modular necks that had been “designed by Cremascoli in 1985”.

100. Prior to April 19, 2005, Wright Medical did not report to the FDA any of the events it received notice of that a Profemur<sup>®</sup> modular neck had fractured in a patient.

101. On or about April 19, 2005, Wright Medical first reported to the FDA that it had received notice that a Profemur<sup>®</sup> modular neck implanted in a patient had fractured.

102. After receiving notice of a 2005 Profemur<sup>®</sup> modular neck fracture, Wright Medical received notice of additional Profemur<sup>®</sup> modular neck fractures in patients.

103. The number of reported titanium Profemur<sup>®</sup> modular neck fractures has continued to increase, and Wright Medical has acknowledge, on the record in open court, more than 700 Profemur<sup>®</sup> modular neck fractures have been reported to it.

104. Prior to December 1, 2008, Wright Medical did not inform all orthopedic surgeons in the United States known by it to have implanted its titanium Profemur<sup>®</sup> modular necks of the reports it had received of titanium modular necks fracturing.

105. On December 1, 2008, a "Safety Alert" was sent by Wright Medical to certain "medical professionals," which stated, in part, "[W]e have received reports of 35 modular neck failures as of November 21, 2008. Initial investigations have revealed several commonalities in these failures: heavyweight males, long modular necks and patient activities such as heavy lifting and impact sports."

106. At the time Wright sent its December 1, 2008 Safety Alert, Wright Medical in fact was aware of more than 35 titanium modular neck failures (by fracture of a Profemur<sup>®</sup> modular neck) as of November 21, 2008, if all of the reported modular neck fractures back to the year 1985 were included in the count.

107. In the FDA Guidance Documents for Femoral Stem Prostheses DRAFT, dated August 1, 1995, available to industry at the time Wright Medical submitted its Abbreviated 510(k)

clearance application for the Pro-Femur R Revision Hip System, the section titled “Contraindicated Weight Limit(s)”, stated, in part, “labeling by contraindication as not for use in patients above a certain weight.”

108. In Wright Medical’s Instructions for Use [hereinafter “IFU”] that accompanied the Profemur<sup>®</sup> hip devices distributed in the United States from the date of their introduction into the United States, through June of 2009, Wright stated the use of these devices to be contraindicated in “obese” patients, “[W]here obesity is defined as three times normal body weight.”

109. Prior to August 2010, Wright Medical did not, in its IFUs for the Profemur<sup>®</sup> hip devices distributed in the United States, include a warning, precaution or other advisory as to the use of any of its Profemur<sup>®</sup> modular necks in people who weighed more than a specifically stated patient body weight in pound or kilograms.

110. Prior to August 2010, Wright Medical did not, in its IFUs for the Profemur<sup>®</sup> hip devices distributed in the United States, include a warning, precaution or other advisory as to the use of any of its Profemur<sup>®</sup> modular necks in people who had a body mass index [BMI] at or above a certain number.

111. Wright Medical has never stated in its IFUs for the Profemur<sup>®</sup> hip devices distributed in the United States that the use of any of its Profemur<sup>®</sup> modular necks was contraindicated in heavyweight males.

112. Wright Medical has never stated in its IFUs for the Profemur<sup>®</sup> devices distributed in the United States that the use of any of its Profemur<sup>®</sup> modular necks was contraindicated in patients who engaged in heavy lifting.

113. Wright Medical has never stated in its IFUs for the Profemur<sup>®</sup> devices distributed in the United States that the use of any of its modular necks was contraindicated in patients who engaged in impact sports.

114. The IFU for Wright Medical Profemur<sup>®</sup> devices distributed in the United States was the same IFU document used for some other Wright Medical hip devices that did not use Profemur<sup>®</sup> Modular necks and were not modular in the region of the artificial femoral neck.

115. At no time did Wright Medical state in its IFUs distributed in the United States that the rate of failure by fracture of the implant was higher for its Profemur<sup>®</sup> modular neck hip devices, compared to the rate of failure by fracture for other Wright Medical hip devices that did not use modular necks, but were subject to the same IFU document.

116. Even though some Wright Medical IFUs for the Profemur<sup>®</sup> devices in use prior to August 2010 contained a section titled, "Conditions presenting increased risk of failure include. . .," that section of the IFU did not state that patients who weigh more than a certain patient body weight, or have a BMI at or above a certain number, or engage in a high level of physical activity, or engage in heavy lifting, or engage in impact sports, would be at an increased risk of failure (by fracture) of the modular neck component, when compared to the risk of failure for other Wright Medical hip devices using that same IFU document but that did not use modular necks.

117. Even though some Wright IFUs for the Profemur<sup>®</sup> devices in use prior to August 2010 contained a section titled "Warning," and a subsection within titled "Modular Necks," Wright Medical did not state therein that patients weighing more than a certain patient body weight, or with a BMI at or above a certain number, or who engage in a high level of physical activity, or engage in heavy lifting, or engage in impact sports, would be at an increased risk of failure (by fracture) of the modular neck component when compared to the risk of failure (by fracture) for

other Wright Medical hip devices using that same IFU document but that did not use modular necks.

118. Even though some Wright IFUs for the Profemur<sup>®</sup> hip devices in use prior to August 2010 contained a section titled “General Product Information,” that stated, “An overweight or obese patient can produce high loads on the prostheses, which can lead to failure of the prosthesis,” and, “If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation of the device, or both,” Wright Medical did not state that patients involved in an occupation or activity that included those activities created any higher risk of failure (by fracture) of the modular neck component when compared to the risk of failure (by fracture) for other Wright Medical hip devices using that same IFU document but that did not use modular necks.

119. Prior to August 2010 Wright Medical did not change the language in its IFUs for its Profemur<sup>®</sup> devices distributed in the United States discussing the issue of any specific patient body weight or activity levels as they may relate to modular neck fractures.

120. Between the dates of December 13, 2000 and August 25, 2009 all of the Profemur<sup>®</sup> modular necks distributed by Wright Medical were made of a titanium alloy, generally known as Ti6Al4V.

121. After Profemur<sup>®</sup> Modular Necks began to be implanted, Cremascoli and Wright Medical began to receive reports of its titanium Profemur<sup>®</sup> modular necks having fractured.

122. After Profemur<sup>®</sup> Modular Necks began to be implanted, Cremascoli and Wright Medical began to receive reports of its titanium Profemur<sup>®</sup> modular necks having fractured at the oblong taper (distal end) where it is seated in the “pocket” of the stem.

123. At some point in time prior to July 30, 2010, Wright Medical came to the conclusion that, "Higher than normal rates of early failure of the long offset PROFEMUR® Titanium Modular Necks have been observed for heavyweight (>230 lbs.) patients."

124. As the number of reported Wright Medical titanium Profemur® modular neck fractures continued to increase, case studies appeared in medical journals reporting the fracture of Wright Medical titanium Profemur® modular necks.

125. Wright Medical titanium Profemur® Modular Necks were fracturing at the neck-stem junction because they were:

- a. Inadequately designed for the patient population for which they were marketed;
- b. Not designed to withstand the stress and loads that they would reasonably be expected to be subjected to after implantation; and
- c. Not designed to meet the performance requirements of published applicable industry standards; and,
- d. Not designed with the performance characteristics that had been represented to surgeons by Wright Medical, and its sales force.

126. As the number of reported Wright Medical titanium Profemur® modular neck fractures continued to increase, surgeons who had been implanting these devices began to question the safety of these devices.

127. As the number of reported Wright Medical titanium Profemur® modular neck fractures continued to increase, some surgeons who had been implanting these devices stopped using the Wright Medical titanium modular necks.

128. As the number of reported Wright Medical titanium Profemur® modular neck fractures continued to increase, at some point in time Wright Medical's sales of its Profemur® hip devices the United States began to decline.

129. As the number of reported Wright Medical titanium Profemur® modular neck fractures continued to increase, Wright Medical did not acknowledge to surgeons or to the FDA that titanium Profemur® modular neck fractures were a result of a defective design.

130. As the number of reported Wright Medical titanium Profemur® modular neck fractures continued to increase, Wright Medical did not acknowledge to surgeons or to the FDA that titanium Profemur® the modular neck fractures that were occurring were a result of an inadequate design for the intended patient population in which that they had been marketed to surgeons as appropriate for.

131. As the number of reported Wright Medical titanium Profemur® modular neck fractures continued to increase, Wright Medical engaged in a campaign of concealment, misinformation, deceit, and fraud, misrepresenting to surgeons the facts and truth as to the numbers, rates, and reasons for its Profemur® modular neck fractures.

132. As the number of reported Wright Medical titanium Profemur® modular neck fractures continued to increase, Wright Medical did not inform all surgeons using these products that, based upon information that had been reported to the FDA MAUDE Database, that the long Profemur® Neck Varus/Valgus 8 Degree, Catalog # PHA0-1254, had the highest numbers of fractures, and the highest rate of fractures, of the modular necks.

133. As the number of reported Wright Medical titanium Profemur® modular neck fractures continued to increase, Wright Medical did not inform the Plaintiff's surgeon that, based upon information that had been reported to the FDA MAUDE Database, that the long Profemur® Neck Varus/Valgus 8 Degree, Catalog # PHA0-1254, had the highest numbers of fractures, and the highest rate of fractures, of the modular necks.

134. As the number of reported Wright Medical titanium Profemur® modular neck fractures continued to increase, Wright Medical began to design and develop a Profemur® modular neck made of a cobalt-chrome alloy [CoCr].

135. One of the purposes of Wright Medical designing and developing a Profemur® modular neck made of CoCr was to preserve its market share of the artificial hip device market.

136. On or about April 16, 2009, Wright Medical submitted to the FDA an Abbreviated 510(k) premarket notification of intent to market what it called Profemur® Hip System Modular Necks. [See: FDA 510(k) K091423.]

137. The modular necks that were the subject of the April 16, 2009, premarket notification of intent to market were made of a CoCr alloy.

138. The modular necks that were the subject of the April 16, 2009, premarket notification of intent to market eventually became known as the Profemur® Plus CoCr Modular Necks.

139. In that premarket notification Profemur® Plus CoCr Modular Necks that Wright Medical represented to the FDA, in part, “The indications for use of the PROFEMUR® Hip System Modular Necks are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices.” [See: FDA 510(k) K091423.]

140. The “predicate devices” referenced in the April 16, 2009 notification of intent to market were the titanium Profemur® titanium modular necks which had received clearance by way of the FDA letter dated December 13, 2003. [See: FDA 510(k) K003016.]

141. It is the position of Wright Medical that the design, development, and introduction of Wright Medical Profemur® Plus CoCr Modular Necks was not a subsequent remedial measure for any design defect that existed in the Wright Medical titanium Profemur® modular necks.

142. Prior to August 25, 2009 Wright Medical knew or should have known that the proposed Profemur® Plus CoCr Modular Necks would be subject to corrosion at the neck-stem junction.

143. Prior to August 25, 2009 Wright Medical knew or should have known that the proposed Profemur® Plus CoCr Modular Necks would be subject to fracture at the neck-stem junction.

144. Prior to August 25, 2009 Wright Medical knew or should have known not to proceed with the development, manufacture and marketing of the proposed Profemur® Plus CoCr Modular Necks.

145. Based upon what Wright Medical knew or should have known as of August 25, 2009, a reasonable manufacturer would not have marketed the Wright Medical Profemur® Plus CoCr Varus/Valgus 8 degree long modular necks, PHAC-1254.

146. On August 25, 2009, Wright Medical received clearance from the FDA to market, in the United States Profemur® modular necks manufactured from CoCr. [See: FDA 510(k) K091423.]

147. Sometime after the date of August 25, 2009, Wright Medical began to market, distribute and sell in the United States Profemur® Plus CoCr Modular Necks.

148. The Wright Medical Profemur® Plus CoCr Modular Necks were marketed to be an alternative for the Wright Medical titanium Profemur® Modular Necks, compatible with all of the same Wright Medical Profemur® stems and Wright Medical Conserve® femoral heads.

149. Wright Medical does not admit that there was, or is, any defect in the design of its titanium Profemur<sup>®</sup> modular necks that leads to premature fracture of its titanium modular necks.

150. Wright Medical does not admit that there was, or is, any defect in the manufacture of its titanium Profemur<sup>®</sup> modular necks that leads to premature fracture of its titanium modular necks.

151. The Profemur<sup>®</sup> Plus CoCr Modular Necks that Wright Medical began to offer to surgeons and patients included a version that was a long Varus/Valgus 8 Degree neck, identified as Catalog # PHAC-1254.

152. The Profemur<sup>®</sup> Plus CoCr Modular Necks that Wright Medical began to offer to surgeons and patients did not include a warning that the titanium version of the long Profemur<sup>®</sup> Varus/Valgus 8 Degree modular neck [Catalog #PHA0-1254] was the version with the highest reported numbers and highest rates of fractures of the neck.

153. The Profemur<sup>®</sup> Plus CoCr Modular Necks that Wright Medical began to offer to surgeons and patients did not include a warning that the CoCr version of the long Profemur<sup>®</sup> Varus/Valgus 8 Degree modular neck [Catalog #PHAC-1254] was the same length and angulation as the titanium version modular neck with the highest reported numbers and highest rates of fractures, the PHA0-1254.

154. The Profemur<sup>®</sup> Plus CoCr Modular Necks that Wright Medical designed and manufactured were designed to be used with the all of the same Profemur<sup>®</sup> hip stems as were its titanium Profemur<sup>®</sup> modular necks.

155. The Profemur<sup>®</sup> Plus CoCr Modular Necks that Wright Medical designed and manufactured were designed to be used with the all of the same femoral heads as were its titanium Profemur<sup>®</sup> modular necks.

156. In marketing its Profemur® Plus CoCr Modular Necks Wright Medical has stated, “Product complaint data reported to Wright to date does not indicate an increased risk, as compared to traditional titanium necks, of adverse events due to taper junction fretting and corrosion or fractures for Profemur® Plus CoCr Modular Necks.” [See Profemur® Plus CoCr Modular Necks Frequently Asked Questions, Wright Medical publication MH619-812.]

157. The claim by Wright Medical in marketing its Profemur® Plus CoCr Modular Necks that, “Product complaint data reported to Wright to date does not indicate an increased risk, as compared to traditional titanium necks, of adverse events due to taper junction fretting and corrosion or fractures for Profemur® Plus CoCr Modular Necks,” was not supported by independent scientific testing.

158. The claim by Wright Medical that “Product complaint data reported to Wright to date does not indicate an increased risk, as compared to traditional titanium necks, of adverse events due to taper junction fretting and corrosion or fractures for Profemur® Plus CoCr Modular Necks” was false and misleading.

159. In marketing its Profemur® Plus CoCr Modular Necks Wright Medical claimed that these CoCr modular necks would result in less fretting than occurred with titanium modular necks.

160. Claims by Wright Medical that these Profemur® Plus CoCr Modular Necks would result in less fretting than occurred with titanium modular necks was not supported by independent scientific testing.

161. Claims by Wright Medical that its Profemur® Plus CoCr Modular Necks would result in less fretting than occurred with titanium modular necks were false and misleading.

162. The design of the Wright Medical Profemur<sup>®</sup> Plus CoCr modular neck, when coupled with the design of the Wright Medical titanium Profemur<sup>®</sup> hip stems, is such that it in fact promotes the process of fretting corrosion at the modular neck/stem junction.

163. In marketing its Profemur<sup>®</sup> Plus CoCr Modular Necks Wright Medical claimed that the use of dissimilar metals, such as the mating of a CoCr modular neck with a titanium stem, would not result in galvanic corrosion (“battery effect”) at a level that would be problematic for patients.

164. Claims by Wright Medical that the mating of a Profemur<sup>®</sup> Plus CoCr Modular Neck with a titanium stem would not result in galvanic corrosion (“battery effect”) at a level that would be problematic for patients, were not supported by unbiased sound scientific testing.

165. Claims by Wright Medical that the mating of its Profemur<sup>®</sup> Plus CoCr Modular Necks with its Profemur<sup>®</sup> titanium stems, would not result in galvanic corrosion (“battery effect”) at a level that would be problematic for patients, were false and misleading.

166. The design of the Wright Medical Profemur<sup>®</sup> Plus CoCr modular neck, when coupled with the design of the Wright Medical titanium Profemur<sup>®</sup> hip stems, is such that it in fact promotes the process of galvanic corrosion (“battery effect”) at the modular neck/stem junction.

167. Prior to offering its Profemur<sup>®</sup> Plus CoCr Modular Necks for distribution or sale in the United States, Wright Medical did not adequately test its design of Profemur<sup>®</sup> Plus CoCr Modular Necks for fretting corrosion after implantation in patients.

168. Prior to offering its Profemur<sup>®</sup> Plus CoCr Modular Necks for distribution or sale in the United States, Wright Medical did not adequately test its design of Profemur<sup>®</sup> Plus CoCr Modular Necks for galvanic corrosion (“battery effect”) after implantation in patients.

169. Prior to offering its Profemur® Plus CoCr Modular Necks for distribution or sale in the United States, Wright Medical did not adequately test its design of Profemur® Plus CoCr Modular Necks for galvanic corrosion (“battery effect”) when mated with titanium Profemur® hip stems after implantation.

170. Wright Medical placed on the market its Profemur® Plus CoCr Modular Necks without having adequately tested them for *in vivo* performance to resist fretting corrosion.

171. Wright Medical placed on the its Profemur® Plus CoCr Modular Necks without having adequately tested them for *in vivo* performance to resist galvanic corrosion.

172. Wright Medical motive in going to market with its Profemur® Plus CoCr Modular Necks to preserve market share and its profits from the sale of its Profemur® hip products.

173. The neck-stem junctions of the Profemur® Plus CoCr Modular Neck PHAC-1254, coupled with a Profemur® titanium hip stem, are subject to significant micromovement which results in significant fretting corrosion, galvanic corrosion, and metal ion release.

174. The neck-stem junctions of the Profemur® Plus CoCr Modular Neck PHAC-1254, coupled with a Profemur® titanium hip stem, and the micromovement which results in significant fretting corrosion, galvanic corrosion, and metal ion release, directly and proximately causes adverse medical conditions which lead to the failure and need for revision of the patient’s hip.

175. C. Lowry Barnes, M.D., is an orthopedic surgeon who had for a time been a paid consultant for Wright Medical.

176. C. Lowry Barnes, M.D., was a named contributor to or author of various Profemur® Surgical Techniques brochures for Wright Medical.

177. At the request of Wright Medical, C. Lowry Barnes, M.D., participated in the design and development of the Wright Medical Profemur® Plus CoCr Modular Necks.

178. Prior to June 18, 2013, C. Lowry Barnes, M.D., informed Wright Medical that its Profemur® Plus CoCr Modular Necks were corroding after implantation in patients.

179. Prior to June 18, 2013, C. Lowry Barnes, M.D., informed Wright Medical that its Profemur® Plus CoCr Modular Necks were corroding after implantation in patients, resulting in the need for revision surgery to remove and replace the patient's implanted Profemur® hip system.

180. Prior to June 18, 2013, C. Lowry Barnes, M.D., informed Wright Medical that its Profemur® Plus CoCr Modular Necks were defective.

181. Prior to June 18, 2013, C. Lowry Barnes, M.D., informed Wright Medical that its Profemur® Plus CoCr Modular Necks should immediately be removed from the market.

182. Wright Medical ignored the recommendations of its paid consultant, C. Lowry Barnes, M.D., and continued to manufacture, distribute and sell its Profemur® Plus CoCr Modular Necks for implantation in patients by orthopedic surgeons.

183. Prior to June 18, 2013, Wright Medical had been informed that its Profemur® Plus CoCr Modular Necks would be subject to corrosion at the neck-stem junction.

184. Prior to June 18, 2013 Wright Medical had been informed that its Profemur® Plus CoCr Modular Necks would be subject to fracture at the neck-stem junction.

185. Prior to June 18, 2013, Wright Medical began to receive notice from surgeons that its Profemur® Plus CoCr Modular Necks were corroding, resulting in the need for revision surgery to remove and replace the patient's implanted Profemur® hip system.

186. Prior to June 18, 2013, Wright Medical received notice that there had been a fracture of a Profemur® Plus CoCr Modular Neck PHAC-1254.

187. As of the date of June 18, 2013, Wright Medical knew or should have known:

- a. It had not adequately tested its Profemur® Plus CoCr Modular Necks to simulate in vivo performance for resistance to fretting corrosion;

- b. It had not adequately tested its Profemur<sup>®</sup> Plus CoCr Modular Necks to simulate in vivo performance for resistance to galvanic corrosion (“battery effect”) its Profemur<sup>®</sup> Plus CoCr Modular Necks would be subject to fretting corrosion;
- c. There was an increased risk of fretting corrosion at the neck-stem junction;
- d. There was an increased risk of galvanic corrosion (“battery effect”) at the neck-stem junction; and,
- e. The Profemur<sup>®</sup> Varus/Valgus 8 degree long modular necks had the highest number, and the highest rate of fracture of the oblong taper in the pocket of the stem.

188. On June 19, 2013, Wright Medical Group, Inc., the parent corporation of Wright Medical Technology, Inc., publicly announced a definitive agreement under which MicroPort Medical B.V., a subsidiary of MicroPort Scientific Corporation, would acquire Wright’s OrthoRecon business, including hip implant products.

189. Upon information and belief, product complaint data reported to Wright Medical prior to January 9, 2014, did indicate an increased risk of adverse events due to taper junction fretting and corrosion for Wright Medical Profemur<sup>®</sup> Plus CoCr Modular Necks when coupled with Wright Medical Profemur<sup>®</sup> hip stems, as compared to traditional titanium necks.

190. Upon information and belief, product complaint data reported to Wright Medical prior to January 9, 2014, did indicate an increased risk of adverse events due to galvanic corrosion (“battery effect”), as compared to traditional titanium necks when coupled with Wright Medical Profemur<sup>®</sup> hip stems.

191. Prior to January 9, 2014, Wright Medical received notice that there had been fractures of Profemur<sup>®</sup> Plus CoCr Modular Necks PHAC-1254.

192. Based upon what Wright Medical knew or should have known as of January 9, 2014, a reasonable manufacturer would have ceased the distribution of the Wright Medical Profemur® Plus CoCr Varus/Valgus 8 degree long modular necks, PHAC-1254, prior to that date.

193. Based upon what Wright Medical knew or should have known as of January 9, 2014, Wright Medical should have ceased the distribution of the Profemur® Plus CoCr Modular Neck PHAC-1254, prior to that date.

194. Based upon what Wright Medical knew or should have known as of January 9, 2014, a reasonable manufacturer would have formally recalled the Profemur® Plus CoCr Modular Neck PHAC-1254, prior to that date.

195. Based upon what Wright Medical knew or should have known as of January 9, 2014, Wright Medical should have formally recalled the Profemur® Plus CoCr Modular Neck PHAC-1254, prior to that date.

196. Based upon what Wright Medical knew or should have known as of January 9, 2014, prior to that date a reasonable manufacturer would have published information that, contrary to claims it had made in the past, product complaint data did indicated that there may be an increased risk of adverse events due to taper junction fretting and corrosion for Wright Medical Profemur® Plus CoCr Modular Necks when coupled with Wright Medical Profemur® hip stems.

197. Based upon what Wright Medical knew or should have known as of January 9, 2014, prior to that date Wright Medical should have informed orthopedic surgeons using its Profemur® hip products that, contrary to claims it had made in the past, product complaint data did indicated that there may be an increased risk of adverse events due to taper junction fretting and corrosion for Wright Medical Profemur® Plus CoCr Modular Necks when coupled with Wright Medical Profemur® hip stems.

198. Based upon what Wright Medical knew or should have known as of January 9, 2014, prior to that date a reasonable manufacturer would have published information that, contrary to claims it had made in the past, product complaint data did indicate that there may be an increased risk of galvanic corrosion (“battery effect”) for Wright Medical Profemur® Plus CoCr Modular Necks when coupled with Wright Medical Profemur® hip stems.

199. Based upon what Wright Medical knew or should have known as of January 9, 2014, prior to that date Wright Medical should have informed orthopedic surgeons using its Profemur® hip products that, contrary to claims it had made in the past, product complaint data did indicate that there may be an increased risk of galvanic corrosion (“battery effect”) for Wright Medical Profemur® Plus CoCr Modular Necks when coupled with Wright Medical Profemur® hip stems.

200. The neck-stem junctions of the Profemur® CoCr modular neck, coupled with a Profemur® titanium hip stem, are subject to significant micromovement which result in fretting corrosion, galvanic corrosion, and metal ion release.

201. The neck-stem junctions of the Profemur® CoCr modular neck, coupled with a Profemur® titanium hip stem, and the micromovement which results in significant fretting corrosion, galvanic corrosion, and metal ion release, directly and proximately causes adverse medical conditions which lead to the failure, fracture of the neck, and need for revision of the hip.

202. Based upon the facts and allegations set forth above, the Profemur® CoCr modular neck and Profemur® hip stem system are defective in their design in that the risks that were inherent in this product being used for hip replacement, when weighed against the utility or benefit derived from the product, outweigh the benefit which might have been gained by placing this defective product in the body of Plaintiff Curtis L. Mahnken.

203. Based upon the facts and allegations set forth above, the Profemur® CoCr modular neck and Profemur® hip stem system are defective in their manufacturing in that they do not comply with their intended design, specifications, in that the risks that were inherent in this product being used for hip replacement, when weighed against the utility or benefit derived from the product, outweigh the benefit which might have been gained by placing this defective product in the body of Plaintiff Curtis L. Mahnken.

204. Based upon the facts and allegations set forth above, the Profemur® CoCr modular neck and Profemur® hip stem system are defective in their labeling in that they do not perform as represented, and the risks that were inherent in this product being used for hip replacement, when weighed against the utility or benefit derived from the product, outweigh the benefit which might have been gained by placing this defective product in the body of Plaintiff Curtis L. Mahnken.

205. Based upon the facts and allegations set forth above, the Profemur® Plus CoCr Modular Necks are unreasonably dangerous in that the risks that were inherent in this product being used for hip replacement, when weighed against the utility or benefit derived from the product, outweigh the benefit which might have been gained by placing this defective product in the body of Plaintiff Curtis L. Mahnken.

206. Defendants Wright Medical Technology, Inc. and MicroPort Orthopedics, Inc., each were negligent in their design, manufacture, distribution and sale, marketing, promotion, and labeling of the Profemur® CoCr modular neck and the Profemur® hip stem system.

207. Defendants Wright Medical Technology, Inc. and MicroPort Orthopedics, Inc., were negligent in the failure to warn patients or surgeons that they had received product complaint data that did indicate an increased risk of adverse events due to taper junction fretting and corrosion.

208. Defendants Wright Medical Technology, Inc. and MicroPort Orthopedics, Inc., were negligent in the failure to warn patients or surgeons that they had received product complaint data that did indicate an increased risk of adverse events due to galvanic corrosion (“battery effect”).

209. Defendant Wright Medical Technology, Inc. was negligent in its failure to cease distribution of the Wright Medical Profemur® CoCr Varus/Valgus 8° long modular necks, Catalog # PHAC-1254, before the date of January 9, 2014.

210. At some point in time before January 9, 2014, Wright Medical began to receive notice that its long Profemur® Plus CoCr Modular Necks PHAC-1254, were fracturing.

211. On January 9, 2014, the Wright Medical OrthoRecon operating segment, was sold for approximately \$285 million.

212. In its form 10-Q, filed with the United States Securities and Exchange Commission, for the quarter ended March 31, 2014, Wright Medical Group, Inc., the parent corporation of Defendant Wright Medical Technology, Inc., states:

On January 9, 2014, pursuant to the previously disclosed Asset Purchase Agreement, dated as of June 18, 2013 (the Purchase Agreement), by and among us, MicroPort Scientific Corporation, a corporation formed under the laws of the Cayman Islands (MicroPort), and MicroPort Medical B.V., a besloten vennootschap formed under the laws of the Netherlands, we completed our divestiture and sale of our business operations operating under the OrthoRecon operating segment (the OrthoRecon Business) to MicroPort. Pursuant to the terms of the Asset Purchase Agreement, the purchase price (as defined in the Purchase Agreement) for the OrthoRecon Business was approximately \$285 million (including an estimated working capital target adjustment), which MicroPort paid in cash.

213. The sale by Wright Medical of its OrthoRecon operating segment to MicroPort included the Wright Medical Profemur® product line, and its manufacturing facilities in Arlington, Tennessee.

214. Prior to the sale by Wright Medical of its OrthoRecon operating segment to MicroPort Ted Davis was the President of the Wright Medical OrthoRecon operating segment.

215. As President of the Wright Medical Wright Medical OrthoRecon operating segment, Ted Davis would have been privy to and knowledgeable about the reports Wright Medical was receiving of adverse clinical events associated with its Profemur Plus CoCr Modular necks.

216. As President of the Wright Medical Wright Medical OrthoRecon operating segment, Ted Davis would have been privy to and knowledgeable about the reports Wright Medical was receiving that its Profemur® Plus CoCr Modular Necks PHAC-1254 were fracturing.

217. Defendant MicroPort Orthopedics, Inc., is the successor in interest to, or the United States operating subsidiary of, MicroPort Scientific Corporation and MicroPort Medical B.V., that had purchased the Wright Medical OrthoRecon operating segment.

218. Upon belief, prior to the sale of the Wright Medical OrthoRecon operating segment to MicroPort on January 9, 2014, Wright Medical did not inform MicroPort that a surgeon who had participated in the design and development of the Wright Medical Profemur® Plus CoCr Modular Necks, C. Lowry Barnes, M.D., had informed Wright Medical that its Profemur® Plus CoCr Modular Necks were corroding after implantation, were defective, and that the Profemur® Plus CoCr Modular Necks should be immediately removed from the market.

219. Upon belief, prior to the sale of the Wright Medical OrthoRecon operating segment to MicroPort on January 9, 2014, Wright Medical did not inform MicroPort that its Profemur® Plus CoCr Modular Necks PHAC-1254 had been reported to be fracturing.

220. At the time of the sale of the Wright Medical OrthoRecon operating segment to MicroPort, Ted Davis became President of MicroPort Orthopedics, Inc.

221. Since the date of January 9, 2014 MicroPort Orthopedics, Inc., has had the obligation to conduct post-market surveillance related to the Profemur<sup>®</sup> hip product line since acquiring those products from Wright Medical in 2014.

222. Under section 522 of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 360, and 21 CFR Part 822, MicroPort was obligated to conduct postmarket surveillance related to the Profemur<sup>®</sup> Plus CoCr Modular Necks, the Profemur<sup>®</sup> LX Hip Stem, and the Conserve Total Femoral head, among other devices.

223. MicroPort failed to comply with requirements of postmarket surveillance study order PS110070, dated May 6, 2011, whereby the Food and Drug Administration (FDA) ordered Wright Medical Technology, Inc. (Wright Medical), former proprietor of MicroPort Orthopedics, Inc. (MicroPort), to conduct postmarket surveillance for the Profemur<sup>®</sup> LX Hip Stem, and the Conserve Total Femoral head, among other devices.

224. As a result of its purchase of the Wright Medical OrthoRecon operating segment on January 9, 2014, MicroPort is legally liable for any design or manufacturing defects that may exist in Wright Medical Profemur<sup>®</sup> Plus CoCr Modular Necks, regardless of when those CoCr modular necks were manufactured, distributed, sold or implanted after that date.

225. Defendant Wright Medical has agreed to defend, indemnify and hold harmless MicroPort for any liability it may have for injuries or damages caused by Profemur<sup>®</sup> Plus CoCr Modular necks that were implanted in any patient before the date of January 9, 2014.

226. At some point in time after January 9, 2014, MicroPort began to receive notice of Profemur<sup>®</sup> Plus CoCr Modular Neck, PHAC-1254, fractures in patients.

227. The fractures of the Profemur<sup>®</sup> Plus CoCr Modular Neck PHAC-1254 were all occurring in the pocket of the Profemur<sup>®</sup> stem.

228. No other versions of the Profemur<sup>®</sup> Plus CoCr Modular Necks have been reported to have fractured, other than the Profemur<sup>®</sup> Plus CoCr Modular Neck PHAC-1254.

229. Prior to March 18, 2015 at least ten Profemur<sup>®</sup> Plus CoCr Modular Necks, PHAC-1254, had ben reported to have fractured.

230. Prior to March 18, 2015, MicroPort was considering recall of the Profemur<sup>®</sup> Plus CoCr Modular Necks, PHAC-1254.

231. While considering a recall of the Profemur<sup>®</sup> Plus CoCr Modular Necks, PHAC-1254 prior to March 18, 2015, MicroPort did not inform surgeons using these devices that it had begun to receive notice of fractures of the Profemur<sup>®</sup> Plus CoCr Modular Necks, PHAC-1254, and those fractures were occurring at the neck-stem junction, similar to the hundreds of fractures that had been reported in with the titanium Profemur Modular Necks.

232. While considering a recall of the Profemur<sup>®</sup> Plus CoCr Modular Necks, PHAC-1254 prior to March 18, 2015, MicroPort did not inform surgeons using these devices that it had begun to receive notice of fractures of the Profemur<sup>®</sup> Plus CoCr Modular Necks, PHAC-1254, and those fractures were occurring at the neck-stem junction, similar to the fractures that had been reported in with the titanium Profemur Modular Necks, PHA0-1254, the version of titanium modular neck with the highest number and highest rate of fracture.

233. On August 7, 2015, MicroPort initiated Class 1 Voluntary Device Product Recall for its Profemur<sup>®</sup> Plus CoCr Modular Neck PHAC-1254.

234. Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

235. MicroPort sent a letter dated August 7, 2015, via FedEx, to all affected customers, wherein they were informed of a voluntary hip replacement recall by MicroPort Orthopedics Inc.; surgeons, managers, distributors and hospitals were instructed to cease distributing and using the Profemur® Plus CoCr Modular Neck PHAC-1254, for hip replacement surgeries.

236. By letter dated August 7, 2015, MicroPort Orthopedics Inc. informed distributors and hospital staff of a voluntary device product recall. Distributors and hospital staff, including risk managers and surgeons, were instructed to stop using and distributing the affected product, and return the recalled product to MicroPort Orthopedics Inc. Distribution Center at 11481 Gulf Stream, Arlington, Tennessee 38002.

237. All lots of the Profemur® Plus CoCr Modular Neck PHAC-1254 were subject to the recall.

238. At the time MicroPort initiated the recall of the Profemur® Plus CoCr Modular Neck PHAC-1254, it reported that 10,489 units was the quantity in commerce.

239. At the time MicroPort initiated the recall of the Profemur® Plus CoCr Modular Neck PHAC-1254, more than 1,000 of these devices had been implanted in patients.

240. After the Class 1 Device Recall of the Profemur Plus CoCr Modular Neck PHAC-1254 was initiated, MicroPort Orthopedics, Inc., terminated Ted Davis as its President and Chief executive officer, September 8, 2015 being his last day of employment.

241. On September 28, 2015 the Class 1 Device Recall of the Profemur Plus CoCr Modular Neck PHAC-1254 was “posted” by the FDA on its [www.accessdata.fda.gov](http://www.accessdata.fda.gov) website.

242. The Profemur® Plus CoCr Modular Neck PHAC-1254 implanted in Plaintiff Curtis L. Mahnken was one of the Profemur® Plus CoCr Modular Necks subject to the Class 1 Device

Recall. Defendant MicroPort, was negligent in its failure to recall the Wright Medical Profemur® CoCr modular neck before the date of March 18, 2015.

**OPPRESSIVE, FRAUDULENT, MALICIOUS  
AND GROSSLY NEGLIGENT CONDUCT**

243. Considering all of the facts, as alleged above, going to market with the Profemur® Plus CoCr Modular Necks is clear and convincing evidence of willful, oppressive, fraudulent, and malicious conduct, was grossly negligent, and demonstrates a complete indifference to, and a conscious disregard for the safety of patients.

244. The failure of Defendant Wright Medical Technology, Inc., to warn patients or surgeons that they had received product complaint data that did indicate an increased risk of fracture with the Profemur® Plus CoCr Modular Necks and adverse events due to taper junction fretting and corrosion, is clear and convincing evidence of willful, oppressive, fraudulent, and malicious conduct, was grossly negligent, and demonstrates a complete indifference to, and a conscious disregard for the safety of patients.

245. The failure of Defendant Wright Medical Technology, Inc., to cease the distribution of the Profemur® Plus CoCr Modular Neck PHAC-1254 before the date of January 9, 2014, is clear and convincing evidence of willful, oppressive, fraudulent, and malicious conduct, was grossly negligent, and demonstrates a complete indifference to, and a conscious disregard for the safety of patients.

246. The failure of Defendant Wright Medical Technology, Inc., to recall Profemur® Plus CoCr Modular Neck PHAC-1254 before the date of January 9, 2014, is clear and convincing evidence of willful, oppressive, fraudulent, and malicious conduct, was grossly negligent, and demonstrates a complete indifference to, and a conscious disregard for the safety of patients.

247. The failure of Defendant Wright Medical Technology, Inc., to heed the advice of its paid consultant, C. Lowry Barnes, M.D., to cease the distribution of the Profemur® Plus CoCr Modular Necks, but to continue to market those devices for implantation by surgeons in patients, is clear and convincing evidence of willful, oppressive, fraudulent, and malicious conduct, was grossly negligent, and demonstrates a complete indifference to, and a conscious disregard for the safety of patients.

248. The failure of Defendant Wright Medical Technology, Inc., to disclose to MicroPort, prior to its purchase of the Profemur® product line on January 9, 2014, the truthful and accurate history of the information and advice it had received about the defects in the Profemur® Plus CoCr Modular Necks, and the risk those products posed to patients, and the fractures that were occurring in the Profemur® Plus CoCr Modular Necks, PHAC-1254, is clear and convincing evidence of willful, oppressive, fraudulent, and malicious conduct, was grossly negligent, and demonstrates a complete indifference to, and a conscious disregard for the safety of patients.

249. The conduct of Ted Davis, who had been the President of the Wright Medical OrthoRecon operating segment, and became the President and CEO of MicroPort, in allowing MicroPort to continue to provide to surgeons for implantation in patients the Profemur® Plus CoCr Modular Necks, PHAC-1254, knowing the truthful and accurate history of the information and advice it had received about the defects in the Profemur® Plus CoCr Modular Necks, and the risk those products posed to patients, and the fractures that were occurring in the Profemur® Plus CoCr Modular Necks, PHAC-1254, is clear and convincing evidence of willful, oppressive, fraudulent, and malicious conduct by MicroPort, was grossly negligent, and demonstrates a complete indifference to, and a conscious disregard for the safety of patients on the part of Defendant MicroPort.

## **WARRANTIES**

### **Wright Medical Titanium Profemur Modular Necks**

250. Statements and representations made by Defendant Wright Medical Technology, Inc., as set forth in this Complaint, constitutes express warranties as to the performance, durability, and capabilities of the Wright Medical Profemur modular necks, and the Wright Medical artificial hip stems they were intended to be used with.

251. By law certain implied warranties of merchantability and fitness for intended use are applicable to the Wright Medical Profemur<sup>®</sup> modular necks, and the Wright Medical artificial hip stems they were intended to be used with.

252. The micromotion, fretting corrosion, galvanic corrosion, and fracture of the Plaintiff Curtis L. Mahnken's Wright Medical Profemur<sup>®</sup> Modular Neck at the junction with the Profemur<sup>®</sup> Stem was a breach of the applicable express warranties of Defendant Wright Medical Technology, Inc.

253. The failure of the Plaintiff Curtis L. Mahnken's Wright Medical Profemur<sup>®</sup> modular neck coupled with the Plaintiff's Wright Medical hip stem was a breach of the applicable express warranties of Defendant Wright Medical Technology, Inc.

254. The micromotion, fretting corrosion, galvanic corrosion, and fracture of the Plaintiff Curtis L. Mahnken's Profemur<sup>®</sup> Modular Neck at the junction with the Profemur<sup>®</sup> Stem was a breach of the applicable implied warranties of merchantability and fitness for intended use by Defendant Wright Medical Technology, Inc.

255. The failure of the Plaintiff Curtis L. Mahnken's Wright Medical Profemur modular neck coupled with the Plaintiff's Wright Medical hip stem was a breach of the applicable implied

warranties of merchantability and fitness for intended use by Defendant Wright Medical Technology, Inc., that are applicable to this product.

**MicroPort Profemur Plus CoCr Modular Necks, PHAC-1254**

256. Statements and representations made by Defendant MicroPort, as set forth in this Complaint, constitutes express warranties as to the performance, durability, and capabilities of the Wright Medical Profemur modular necks, and the MicroPort artificial hip stems they were intended to be used with.

257. By law certain implied warranties of merchantability and fitness for intended use are applicable to the MicroPort Profemur® Plus CoCr Modular Necks, PHAC-1254, and the artificial hip stems they were intended to be used with.

258. The micromotion, fretting corrosion, galvanic corrosion, and fracture of the Plaintiff Curtis L. Mahnken's MicroPort Profemur® Plus CoCr Modular Necks, PHAC-1254, at the junction with the Profemur® Stem was a breach of the applicable express warranties of Defendant MicroPort.

259. The failure of the Plaintiff Curtis L. Mahnken's the MicroPort Profemur® Plus CoCr Modular Necks, PHAC-1254, coupled with the Plaintiff's Profemur® hip stem, was a breach of the applicable express warranties of Defendant MicroPort.

260. The micromotion, fretting corrosion, galvanic corrosion, and fracture of the Plaintiff Curtis L. Mahnken's MicroPort Profemur® Plus CoCr Modular Necks, PHAC-1254, at the junction with the Profemur® Stem was a breach of the applicable implied warranties of merchantability and fitness for intended use by Defendant MicroPort.

261. The failure of the Plaintiff Curtis L. Mahnken's Profemur® Plus CoCr Modular Necks, PHAC-1254, coupled with the Plaintiff's Profemur® hip stem was a breach of the

applicable implied warranties of merchantability and fitness for intended use by Defendant MicroPort, that are applicable to this product.

#### **PLAINTIFF'S INJURIES AND DAMAGES**

262. On or about March 16, 2015, due to micromotion and fretting corrosion of the oblong taper of the Wright Medical titanium Profemur<sup>®</sup> Modular Neck where it seated in the pocket of the Profemur<sup>®</sup> stem, the Wright Medical Profemur<sup>®</sup> Modular Neck implanted in Plaintiff Curtis L. Mahnken's hip catastrophically failed, breaking into two pieces, causing physical injury to the Plaintiff.

263. On or about January 27, 2018, due to micromotion and fretting corrosion of the oblong taper of the Profemur<sup>®</sup> Plus CoCr, PHAC-1254 Modular Neck where it seated in the pocket of the Profemur<sup>®</sup> stem, the Profemur<sup>®</sup> Plus CoCr Modular Neck implanted in Plaintiff Curtis L. Mahnken's hip catastrophically failed, breaking into two pieces, causing physical injury to the Plaintiff.

264. As a direct and proximate result of the conduct of Defendant Wright Medical Technology, Inc., and the conduct of Defendant MicroPort Orthopedics, Inc., as set forth in this Complaint, Plaintiff Curtis L. Mahnken sustained injuries and damages including, but not limited to undergoing surgeries to remove and replace his failed Profemur hip devices; past and future pain and anguish, both in mind and in body; permanent diminishment of his ability to participate in and enjoy the affairs of life; medical bills associated with the replacement procedure and recovery therefrom; future medical expenses; loss of enjoyment of life; loss of past and future earnings and earning capacity; disfigurement; physical impairment, and other injuries not fully known at this time.

265. Plaintiff Curtis L. Mahnken's injuries suffered were both factually and proximately caused by the defective products of the Defendant Wright Medical Technology, Inc.

266. Plaintiff Curtis L. Mahnken's injuries suffered were both factually and proximately caused by the unreasonably dangerous products of the Defendant Wright Medical Technology, Inc.

267. Plaintiff Curtis L. Mahnken's injuries suffered were both factually and proximately caused by the defective products of the Defendant Defendant MicroPort Orthopedics, Inc.

268. Plaintiff Curtis L. Mahnken's injuries suffered were both factually and proximately caused by the unreasonably dangerous products of the Defendant MicroPort Orthopedics, Inc.

269. Plaintiff Curtis L. Mahnken is entitled to recover for all economic and special damages incurred, including but not limited to damages for subsequent surgeries, rehabilitative services, follow up doctor visits and all expenditures incurred as a result of the additional operations and follow up procedures.

270. Plaintiff Curtis L. Mahnken is entitled to recovery for lost wages, having been disabled and diminished ability to earn income.

271. Plaintiff Curtis L. Mahnken is entitled to compensation for permanent disability as a result of the failure of this hip replacement device which caused substantial injury.

272. Plaintiff Curtis L. Mahnken further shows that he is entitled to recover for all noneconomic and compensatory damages allowed by law, including, but not limited to, pain and suffering for all pain and suffering that he has incurred as a result of the defective product, the follow-up surgery, rehabilitation, and constant pain that occurs as a result of the failure of the product.

#### **LIABILITY**

**COUNT I**  
**NEGLIGENCE of WRIGHT MEDICAL**  
**Titanium Profemur® Modular Neck**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in this Complaint.

273. Defendant Wright Medical Technology, Inc., owed a duty of reasonable care to the general public, including the Plaintiff, when it designed, manufactured, assembled, inspected, tested, marketed, placed into the stream of commerce, and sold the titanium Wright Medical Profemur® Varus/Valgus 8 degree long Profemur modular neck, part number PHA0-1254, and the Wright Medical Profemur® Total Hip System, to assure that the Wright Medical Profemur® modular neck, and the Wright Medical Profemur® Total Hip System were not defective and/or unreasonably dangerous for their intended purposes and foreseeable uses.

274. Defendant Wright Medical Technology, Inc., breached this duty by designing, manufacturing, assembling, inspecting, testing, labeling, marketing, distributing and selling the titanium Wright Medical Profemur® Modular Neck, and the Wright Medical Profemur® Total Hip System in a defective and unreasonably unsafe condition including, but not limited to, its propensity for metal on metal failure.

275. Defendant Wright Medical Technology, Inc., owed Plaintiff a duty of reasonable care to:

- a. Adequately design the Wright Medical Profemur® hip system so that it would not fracture at the neck-stem junction when being used as intended and expected in the intended patient population;
- b. Adequately test the Wright Medical Profemur® hip system to ensure that it was adequately designed and would not fracture at the neck-stem junction when being used as intended and expected in the intended patient population;

- c. Reasonably label and market the Wright Medical Profemur® hip system so as to not misrepresent the clinical history of the Profemur modular necks fracturing;
- d. Reasonably label and market the Wright Medical Profemur® hip system so as to not misrepresent the patient population that these devices were intended to be implanted in;
- e. Reasonably label and market the Wright Medical Profemur® hip system so as to not misrepresent the performance characteristics of these devices;
- f. Discover the defect(s) and to inform and/or warn Plaintiff, or his surgeons, of any defect(s), once discovered; and,
- g. Discover the misrepresentation(s) and to inform and/or warn Plaintiff, or his surgeons, of any misrepresentation(s), once discovered.

276. The conduct, actions, inactions, concealment, and misrepresentations of Defendant Wright Medical Technology, Inc., as set forth above in this Complaint, were and are a breach of these duties, and is negligence.

277. Defendant Wright Medical Technology, Inc., otherwise was negligent in the particulars set forth in this Complaint, and such negligence was a direct and proximate cause of the incident and injuries set forth herein.

278. The negligence of Defendant Wright Medical Technology, Inc., as set forth in this Complaint, directly and proximately caused the injuries and damages alleged in this Complaint.

**COUNT II**  
**NEGLIGENCE of WRIGHT MEDICAL, and MICROPORT**  
**Profemur® Plus CoCr Modular Neck**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in this Complaint.

279. Defendant Wright Medical Technology, Inc., owed a duty of reasonable care to the general public, including the Plaintiff, when it designed the Profemur® Plus CoCr Modular Neck, PHAC-1254, to assure that the Profemur® CoCr modular neck, when mated with the Wright Medical Profemur® Total Hip System, were not defective and/or unreasonably dangerous for their intended purposes and foreseeable uses.

280. Defendant Wright Medical Technology, Inc., breached its duty of reasonable care to the general public, including the Plaintiff, when it designed the Profemur® Plus CoCr Modular Neck, PHAC-1254, in that the Profemur® CoCr modular neck, when mated with the Wright Medical Profemur® Total Hip System, is defective and/or unreasonably dangerous for their intended purposes and foreseeable uses.

281. Defendant Wright Medical Technology, Inc., owed a duty of reasonable care to the general public, including the Plaintiff, when it manufactured the Profemur® Plus Modular Neck, PHAC-1254, to assure that the Profemur® Plus CoCr modular neck, when mated with the Wright Medical Profemur® Total Hip System, was:

- a. Manufactured in conformance with its intended design specifications;
- b. Manufactured without defects; and,
- c. Not defective and/or unreasonably dangerous for their intended purposes and foreseeable uses.

282. Defendant Wright Medical Technology, Inc., breached its duty of reasonable care to the general public, including the Plaintiff, when it manufactured the Profemur® Plus Modular Neck, PHAC-1254, in that the Profemur® Plus CoCr modular neck, when mated with the Wright Medical Profemur® Total Hip System, were:

- a. Not manufactured in conformance with its intended design specifications;

- b. Manufactured with defects; and,
- c. Were defective and/or unreasonably dangerous for their intended purposes and foreseeable uses.

283. Defendant Wright Medical Technology, Inc., owed Plaintiff a duty of reasonable care to discover the defect(s) in design and to inform and/or warn Plaintiff, or his surgeons, of the defect(s) once it or they were discovered, and Defendants failed to do so further placing Plaintiff at risk for harm and injury.

284. Defendant Wright Medical Technology, Inc., owed Plaintiff a duty of reasonable care to discover the defect(s) in manufacture of the PHAC-1254 modular neck and to inform and/or warn Plaintiff, or his surgeons, of the defect(s) once it or they were discovered, and Defendants failed to do so further placing Plaintiff at risk for harm and injury.

285. Defendant Wright Medical Technology, Inc., breached its duty of reasonable care in that it did not discover the defects and inform and/or warn Plaintiff, or his surgeons, of the defects once it was discovered, placing Plaintiff at risk for harm and injury.

286. Defendant MicroPort Orthopedics, Inc., owed Plaintiff a duty of reasonable care to discover the defects and to inform and/or warn Plaintiff, or his surgeons, of the defects once discovered, and Defendants failed to do so further placing Plaintiff at risk for harm and injury.

287. Defendant MicroPort Orthopedics, Inc., breached its duty of reasonable care in that it did not discover the defects and to inform and/or warn Plaintiff, or his surgeons, of the defects once discovered, placing Plaintiff at risk for harm and injury.

288. Defendant Wright Medical Technology, Inc., owed a duty of reasonable care to:

- a. Timely inform surgeons using its products of the issue of corrosion at the neck-stem junction with the Profemur® Plus CoCr Modular Necks;

- b. Remove the Profemur® Plus CoCr Modular Neck, PHAC-1254 from the market once it became aware of the issue of corrosion at the neck-stem junction;
- c. Recall Profemur® Plus CoCr Modular Neck, PHAC-1254, from the market once it became aware of the issue of corrosion at the neck-stem junction;
- d. Timely inform surgeons, including the plaintiff's surgeon, including the Plaintiff's surgeon, of the issue of fractures at the neck-stem junction with the Profemur® Plus CoCr Modular Necks, PHAC-1254;
- e. Remove the Profemur® Plus CoCr Modular Neck, PHAC-1254, from the market once it became aware of the issue of fractures at the neck-stem junction.
- f. Once it became aware of the issue of corrosion at the neck-stem junction of the Profemur® Plus CoCr Modular Neck, to inform MicroPort of that issue before MicroPort purchased the Wright Medical OrthoRecon operating segment.
- g. Once it became aware of the issue of fractures at the neck-stem junction of the Profemur® Plus CoCr Modular Neck, PHAC-1254, to inform MicroPort of that issue before MicroPort Purchased the Wright Medical OrthoRecon operating segment.

289. Defendant Wright Medical Technology, Inc., breached these duties of reasonable care in that it failed to:

- a. Timely inform surgeons using its products of the issue of corrosion at the neck-stem junction with the Profemur® Plus CoCr Modular Necks;
- b. Remove the Profemur® Plus CoCr Modular Neck, PHAC-1254 from the market once it became aware of the issue of corrosion at the neck-stem junction;
- c. Recall Profemur® Plus CoCr Modular Neck, PHAC-1254, from the market once it became aware of the issue of corrosion at the neck-stem junction;

- d. Timely inform surgeons using its products of the issue of fractures at the neck-stem junction with the Profemur® Plus CoCr Modular Necks, PHAC-1254;
- e. Remove the Profemur® Plus CoCr Modular Neck, PHAC-1254, from the market once it became aware of the issue of fractures at the neck-stem junction.
- f. Timely inform MicroPort once it became aware of the issue of corrosion at the neck-stem junction of the Profemur® Plus CoCr Modular Neck, before MicroPort purchased the Wright Medical OrthoRecon operating segment.
- g. Timely inform MicroPort once it became aware of the issue of fractures at the neck-stem junction of the Profemur® Plus CoCr Modular Neck, PHAC-1254, before MicroPort Purchased the Wright Medical OrthoRecon operating segment.

290. Defendant MicroPort Orthopedics, Inc., owed a duty of reasonable care to:

- a. Timely inform surgeons using its products of the issue of corrosion at the neck-stem junction with the Profemur® Plus CoCr Modular Necks;
- b. Remove the Profemur® Plus CoCr Modular Neck, PHAC-1254 from the market once it became aware of the issue of corrosion at the neck-stem junction;
- c. Recall Profemur® Plus CoCr Modular Neck, PHAC-1254, from the market once it became aware of the issue of corrosion at the neck-stem junction;
- d. Timely inform surgeons using its products, including the Plaintiff's surgeon, of the issue of fractures at the neck-stem junction with the Profemur® Plus CoCr Modular Necks, PHAC-1254; and,
- e. Remove the Profemur® Plus CoCr Modular Neck, PHAC-1254, from the market once it became aware of the issue of fractures at the neck-stem junction.

291. Defendant MicroPort Orthopedics, Inc., breached these duties of reasonable care in

that it failed to:

- a. Timely inform surgeons using its products of the issue of corrosion at the neck-stem junction with the Profemur® Plus CoCr Modular Necks;
- b. Remove the Profemur® Plus CoCr Modular Neck, PHAC-1254 from the market once it became aware of the issue of corrosion at the neck-stem junction;
- c. Recall Profemur® Plus CoCr Modular Neck, PHAC-1254, from the market once it became aware of the issue of corrosion at the neck-stem junction;
- d. Timely inform surgeons using its products of the issue of fractures at the neck-stem junction with the Profemur® Plus CoCr Modular Necks, PHAC-1254; and,
- e. Remove the Profemur® Plus CoCr Modular Neck, PHAC-1254, from the market once it became aware of the issue of fractures at the neck-stem junction.

292. The conduct actions, inactions, concealment, and misrepresentations of Defendant Wright Medical Technology, Inc., and Defendant MicroPort Orthopedics, Inc., as set forth above in this Complaint, were and are a breach of these duties, and is negligence.

293. Defendant Wright Medical Technology, Inc., and Defendant MicroPort Orthopedics, Inc., otherwise were each negligent in the particulars set forth in this Complaint.

294. The negligence of Defendant Wright Medical Technology, Inc., and Defendant MicroPort Orthopedics, Inc., as set forth in this Complaint, directly and proximately caused the injuries and damages alleged in this Complaint.

**COUNT III**  
**NEGLIGENCE of MICROPORT**  
**Profemur® Plus CoCr Modular Neck**  
**(Conduct of Jamie Sease)**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in this Complaint.

295. Defendant MicroPort, as the distributor of the Profemur<sup>®</sup> Plus CoCr Modular Neck, PHAC-1254, and with its employee, Jamie Sease, having previously been a direct employee and Product Development Engineer of Wright Medical Profemur<sup>®</sup> hip products in the past, knew or should have known history of the titanium Profemur<sup>®</sup> Modular Neck PHA0-1254 fractures, and the history of the Profemur<sup>®</sup> Plus CoCr Modular Neck neck-stem corrosion, and the history of the Profemur<sup>®</sup> Plus CoCr Modular Neck PHAC-1254 fractures.

296. Defendant MicroPort, as the distributor of the Profemur<sup>®</sup> Plus CoCr Modular Neck, PHAC-1254, and with its employee, Jamie Sease, having been a direct employee and Product Development Engineer of Wright Medical Profemur<sup>®</sup> hip products in the past, owed a duty of reasonable care to the Plaintiff, and to his surgeon, to disclose to disclose, prior to the Plaintiff's March 18, 2015 revision hip surgery:

- a. The Profemur<sup>®</sup> Modular Neck PHA0-1254 was the version of Profemur Modular neck that had the highest number of fractures, and the highest rate of fractures;
- b. The Profemur<sup>®</sup> Plus CoCr Modular Neck PHAC-1254 was the same length and angulation as the PHA0-1254 modular neck;
- c. There were clinical reports of the Profemur<sup>®</sup> Plus CoCr Modular Necks PHAC-1254 having fractured at the neck-stem junction; and,
- d. There were clinical reports of the Profemur<sup>®</sup> Plus CoCr Modular Necks having corroded at the neck-stem junction when mated with Profemur<sup>®</sup> titanium hip stems, resulting in revision of the hip joint.

297. Defendant MicroPort, as the distributor of the Profemur<sup>®</sup> Plus CoCr Modular Neck, PHAC-1254, and with its employee, Jamie Sease, having been a direct employee and Product Development Engineer of Wright Medical Profemur<sup>®</sup> hip products in the past, breached its duty

of reasonable care to the Plaintiff, and to his surgeon, by failing to disclose to Plaintiff's Surgeon, prior to the Plaintiff's March 18, 2015 revision hip surgery:

- a. The Profemur® Modular Neck PHA0-1254 was the version of Profemur Modular neck that had the highest number of fractures, and the highest rate of fractures;
- b. The Profemur® Plus CoCr Modular Neck PHAC-1254 was the same length and angulation as the PHA0-1254 modular neck;
- c. There were clinical reports of the Profemur® Plus CoCr Modular Necks PHAC-1254 having fractured at the neck-stem junction.
- d. There were clinical reports of the Profemur® Plus CoCr Modular Necks having corroded at the neck-stem junction when mated with Profemur® titanium hip stems, resulting in revision of the hip joint; and,
- e. There were clinical reports of the Profemur® Plus CoCr Modular Necks PHAC-1254 having fractured at the neck-stem junction.

298. Defendant MicroPort, as the distributor of the Profemur® Plus CoCr Modular Neck, PHAC-1254, and with its employee, Jamie Sease, having been a direct employee and Product Development Engineer of Wright Medical Profemur® hip products in the past, was otherwise negligent in the particulars set forth in this Complaint.

299. The negligence of Defendant MicroPort Orthopedics, Inc., as set forth in this Complaint, directly and proximately caused the injuries and damages alleged in this Complaint.

**COUNT IV**  
**NEGLIGENCE of PELLMED, LLC.**  
**Profemur® Plus CoCr Modular Neck**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in this Complaint.

300. Defendant PellMed, LLC, as the distributor of the Profemur<sup>®</sup> Plus CoCr Modular Neck, PHAC-1254, and with its owner, officer, and director, Chuck Pellegrino having been a direct employee and sales representative of Wright Medical Profemur<sup>®</sup> hip products in the past, knew or should have known history of the titanium Profemur<sup>®</sup> Modular Neck PHA0-1254 fractures, and the history of the Profemur<sup>®</sup> Plus CoCr Modular Neck neck-stem corrosion, and the history of the Profemur<sup>®</sup> Plus CoCr Modular Neck PHAC-1254 fractures.

301. Defendant PellMed, LLC, as the distributor of the Profemur<sup>®</sup> Plus CoCr Modular Neck, PHAC-1254, and with its owner, officer, and director, Chuck Pellegrino, having been a direct employee of Weight Medical, and having been trained by Wright Medical to be a Profemur<sup>®</sup> hip product sales representative in the past, owed a duty of reasonable care to the Plaintiff, and to his surgeon, to disclose to disclose, prior to the Plaintiff's March 18, 2015 revision hip surgery:

- a. The Profemur<sup>®</sup> Modular Neck PHA0-1254 was the version of Profemur Modular neck that had the highest number of fractures, and the highest rate of fractures;
- b. The Profemur<sup>®</sup> Plus CoCr Modular Neck PHAC-1254 was the same length and angulation as the PHA0-1254 modular neck;
- c. There were clinical reports of the Profemur<sup>®</sup> Plus CoCr Modular Necks PHAC-1254 having fractured at the neck-stem junction; and,
- d. There were clinical reports of the Profemur<sup>®</sup> Plus CoCr Modular Necks having corroded at the neck-stem junction when mated with Profemur<sup>®</sup> titanium hip stems, resulting in revision of the hip joint.

302. Defendant PellMed, LLC, as the distributor of the Profemur<sup>®</sup> Plus CoCr Modular Neck, PHAC-1254, and with its owner, officer, and director, Chuck Pellegrino, having been a direct employee of Weight Medical, and having been trained by Wright Medical to be a Profemur<sup>®</sup> hip product sales representative in the past, breached its duty of reasonable care to the Plaintiff, and to his surgeon, by failing to disclose to Plaintiff's Surgeon, prior to the Plaintiff's March 18, 2015 revision hip surgery:

- a. The Profemur<sup>®</sup> Modular Neck PHA0-1254 was the version of Profemur Modular neck that had the highest number of fractures, and the highest rate of fractures;
- b. The Profemur<sup>®</sup> Plus CoCr Modular Neck PHAC-1254 was the same length and angulation as the PHA0-1254 modular neck;
- c. There were clinical reports of the Profemur<sup>®</sup> Plus CoCr Modular Necks PHAC-1254 having fractured at the neck-stem junction; and,
- d. There were clinical reports of the Profemur<sup>®</sup> Plus CoCr Modular Necks having corroded at the neck-stem junction when mated with Profemur<sup>®</sup> titanium hip stems, resulting in revision of the hip joint.

303. Defendant PellMed, LLC, as the distributor of the Profemur<sup>®</sup> Plus CoCr Modular Neck, PHAC-1254, and with its owner, officer, and director, Chuck Pellegrino, having been a direct employee of Weight Medical, and having been trained by Wright Medical to be a Profemur<sup>®</sup> hip product sales representative in the past, was otherwise negligent in the particulars set forth in this Complaint.

304. The negligence of Defendant PellMed, LLC, as set forth in this Complaint, directly and proximately caused the injuries and damages alleged in this Complaint.

**COUNT V**  
**STRICT PRODUCTS LIABILITY**  
**for**  
**DEFECTIVE DESIGN and FAILURE TO WARN**  
**by**  
**WRIGHT MEDICAL**  
**for the Titanium Profemur® Modular Neck**

305. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

306. The titanium Wright Medical Profemur® Modular Neck, and the Wright Medical Profemur® Total Hip System, used in Plaintiff's index hip replacement surgery were not reasonably safe for their intended uses and were defective as described herein with respect to the design.

307. The Wright Medical titanium Profemur® Modular Neck, and the Wright Medical Profemur® Total Hip System, possessed defective and dangerous characteristics, as described herein, and the Defendant Wright Medical Technology, Inc., failed to use reasonable care to provide an adequate warning of such characteristics and their dangers to health care providers and patients, including Plaintiff.

308. At the time of the incident set forth herein, the Wright Medical Profemur® Modular Neck, and the Wright Medical Profemur® Total Hip System were dangerous to an extent beyond that which would be contemplated by the ordinary health care provider, and patient, with the ordinary knowledge common to the medical community as to the products' characteristics.

309. Health care providers and patients, including Plaintiff, did not know and should not have been expected to know of the dangerous characteristics of the Wright Medical titanium Profemur® Modular Neck, and the Wright Medical Profemur® Total Hip System, which had the potential to cause injury and damage.

310. As a direct and proximate result of the Defendant Wright Medical Technology, Inc.'s, failure to warn, Plaintiff sustained serious injuries and was damaged.

311. To the extent that Defendant MicroPort Orthopedics, Inc., has assumed or acquired legal liability related to the Wright Medical Profemur® CoCr long varus/valgus 8 degree modular neck, part number PHAC-1254, by its acquisition of the Wright Medical OrthoRecon operating segment in January 2014, Defendant MicroPort Orthopedics, Inc., is liable to the Plaintiff for the conduct, injuries, and damages alleged in this count of this Complaint.

312. The conduct of Defendant Wright Medical Technology, Inc., as set forth in this Complaint, directly and proximately caused the injuries and damages alleged in this Complaint.

**COUNT VI**  
**STRICT PRODUCTS LIABILITY**  
**for**  
**DEFECTIVE DESIGN and/or MANUFACTURE and/or FAILURE TO WARN**  
**by**  
**WRIGHT MEDICAL and MICROPORT**  
**Profemur® Plus CoCr Modular Neck PHAC-1254**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

313. Profemur® Plus CoCr Modular Neck, PHAC-1254, and the Profemur® Total Hip System used in Plaintiff's revision hip surgery were not reasonably safe for their intended uses and were defective as described herein with respect to the design.

314. Profemur® Plus CoCr Modular Neck, PHAC-1254, and the Profemur® Total Hip System used in Plaintiff's revision hip surgery were not reasonably safe for their intended uses and were defective as described herein with respect to their manufacture.

315. To the extent that Defendant MicroPort Orthopedics, Inc., has assumed or acquired legal liability related to the Wright Medical Profemur® Plus CoCr Modular Neck, PHAC-1254, by its acquisition of the Wright Medical OrthoRecon operating segment in January 2014, Defendant MicroPort Orthopedics, Inc., is liable to the Plaintiff for the conduct, injuries, and damages alleged in this count of this Complaint attributable Defendant Wright Medical.

316. The conduct of Defendant Wright Medical Technology, Inc., and MicroPort Orthopedics, Inc., as set forth in this Complaint, directly and proximately caused the injuries and damages alleged in this Complaint.

317. The Wright Medical Profemur® Plus Modular Neck, PHAC-1254, and the Wright Medical Profemur® Total Hip System were further rendered unreasonably dangerous because the Defendant Wright Medical Technology, Inc., and Defendant MicroPort, failed to provide an adequate warning to surgeons, and to the Plaintiff, regarding the hazards associated with the reasonable and foreseeable use of Wright Medical Profemur® Plus Modular Neck, PHAC-1254, and the Wright Medical Profemur® Total Hip System.

318. The Wright Medical Profemur® Plus Modular Neck, PHAC-1254, and the Wright Medical Profemur® Total Hip System, possessed defective and dangerous characteristics, as described herein, which caused damage, and the Defendant Wright Medical Technology, Inc., failed to use reasonable care to provide an adequate warning of such characteristics and their dangers to health care providers and patients, including Plaintiff.

319. At the time of the incident set forth herein, the Wright Medical Profemur® Plus Modular Neck, PHAC-1254, and the Wright Medical Profemur® Total Hip System, were dangerous to an extent beyond that which would be contemplated by the ordinary health care

provider and patient, with the ordinary knowledge common to the medical community as to the products' characteristics.

320. Health care providers and patients, including Plaintiff, did not know and should not have been expected to know of the dangerous characteristics of the Wright Medical Profemur® Plus Modular Neck, PHAC-1254, and the Wright Medical Profemur® Total Hip System, which had the potential to cause injury and damage.

321. As a direct and proximate result of the Defendant Wright Medical Technology, Inc.'s, failure to warn, Plaintiff sustained serious injuries and was damaged.

322. To the extent that Defendant MicroPort Orthopedics, Inc., has assumed or acquired legal liability related to the Wright Medical Profemur® CoCr long varus/valgus 8 degree modular neck, part number PHAC-1254, by its acquisition of the Wright Medical OrthoRecon operating segment in January 2014, Defendant MicroPort Orthopedics, Inc., is liable to the Plaintiff for the conduct, injuries, and damages alleged in this count of this Complaint.

**COUNT VII**  
**BREACH OF WARRANTY**  
**WRIGHT MEDICAL and MICROPORT**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

323. Defendant Wright Medical Technology, Inc., and MicroPort Orthopedics, Inc., each warranted, both expressly and impliedly, through their marketing, advertising, distributors and sales representatives, that Profemur® Modular Necks, and the Profemur® Total Hip System were of merchantable quality, fit for the ordinary purposes and uses for which they were sold.

324. The Defendant Wright Medical Technology, Inc., and MicroPort Orthopedics, Inc., each were aware that orthopedic surgeons, including the plaintiff's orthopedic surgeons rely upon the representations made by the Defendants and their representatives when choosing, selecting and purchasing its products, including the Profemur<sup>®</sup> Modular Necks, and the Profemur<sup>®</sup> Total Hip System.

325. Due to the defective and unreasonably dangerous design and manufacture of the Wright Medical titanium Profemur<sup>®</sup> Modular Neck, PHA0-1254, and the Wright Medical Profemur<sup>®</sup> Total Hip System, it was neither of merchantable quality nor fit for the ordinary purposes for which it was sold, presenting an unreasonable risk of injury to patients, including Plaintiff, for expected and foreseeable use.

326. Due to the defective and unreasonably dangerous design and manufacture of the Profemur<sup>®</sup> Plus CoCr Modular Neck, PHAC-1254, and the Wright Medical Profemur<sup>®</sup> Total Hip System, it was neither of merchantable quality nor fit for the ordinary purposes for which it was sold, presenting an unreasonable risk of injury to patients, including Plaintiff, for expected and foreseeable use.

327. The defective and unreasonably dangerous condition of the Wright Medical titanium Profemur<sup>®</sup> Modular Neck, PHA0-1254, and the Wright Medical Profemur<sup>®</sup> Total Hip System, constituted a breach of the Defendant Wright Medical Technology, Inc.'s express and implied warranties, and such breach was a direct and proximate cause of the incident and injuries described herein.

328. The defective and unreasonably dangerous condition of the Wright Medical Profemur<sup>®</sup> Plus CoCr Modular Neck, PHAC-1254, and the Wright Medical Profemur<sup>®</sup> Total Hip System constituted a breach of the Defendant Wright Medical Technology, Inc.'s and MicroPort

Orthopedics, Inc., express and implied warranties, and such breach was a direct and proximate cause of the incident and injuries described herein.

329. To the extent that Defendant MicroPort Orthopedics, Inc., has assumed or acquired legal liability related to the Wright Medical Profemur® CoCr long varus/valgus 8 degree modular neck, part number PHAC-1254, by its acquisition of the Wright Medical OrthoRecon operating segment in January 2014, Defendant MicroPort Orthopedics, Inc., is liable to the Plaintiff for the conduct, injuries, and damages alleged in this count of this Complaint.

**COUNT VIII**  
**NEGLIGENT and INTENTIONAL MISREPRESENTATION; FRAUD**  
**by**  
**WRIGHT MEDICAL**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

330. Defendant Wright Medical Technology, Inc., had a duty to accurately and truthfully disclose and represent to surgeons, Plaintiff, and the public, the clinical history of the Wright Medical titanium Profemur® modular necks.

331. The representations as to the clinical history of the Wright Medical titanium Profemur® modular necks that the Defendant Wright Medical Technology, Inc., made to surgeons, as set forth above,

The modular neck used with the Profemur® Hip has been employed by Wright Cremascoli for over 15 years. The necks were designed in 1985 and have been successfully implanted in over 50,000 patients requiring both primary and revision hip procedures. The necks are used in other Wright Cremascoli hip systems besides the Profemur® Hip. *None of the necks has experienced a clinical failure since their inception.* [emphasis added]

were false when made, and Wright Medical knew that they were false when made.

332. Defendant Wright Medical Technology, Inc., knew that surgeons would rely on the clinical history of the Profemur® modular necks it provided in deciding to use, or deciding to continue to use, the Profemur® products in their patients.

333. The conduct of Defendant Wright Medical Technology, Inc., in making the false representations of the clinical history of the Profemur® modular necks, and continuing to make that false representation, was negligent.

334. The conduct of Defendant Wright Medical Technology, Inc., in making the false representations of the clinical history of the Profemur® modular necks, and continuing to make that false representation, was an intentional misrepresentation.

335. The conduct of Defendant Wright Medical Technology, Inc., in making the false representations of the clinical history of the Profemur® modular necks, and continuing to make that false representation, was fraud.

336. Wright Medical Technology, Inc., had a duty to accurately and truthfully disclose to surgeons using its Profemur hip products, the clinical history of fractures of the Profemur® Plus CoCr Modular Neck, PHA0-1254, and neck-stem corrosion with the Profemur® Plus CoCr Modular Necks, before the purchase by MicroPort of its Profemur® Product line.

337. Had Defendant Wright Medical Technology, Inc., accurately and truthfully disclosed to surgeons using its Profemur hip products, the clinical history of fractures of the Profemur® Plus CoCr Modular Neck, PHA0-1254, and neck-stem corrosion with the Profemur® Plus CoCr Modular Necks, before the purchase by MicroPort of its Profemur® Product line, Plaintiff's surgeon would not have used a Profemur® Plus CoCr Modular Neck PHAC-1254 for Plaintiff's March 18, 2015 revision hip surgery.

338. The conduct of Defendant Wright Medical Technology, Inc., in not disclosing to surgeons, prior to the sale of the Profemur<sup>®</sup> Product line to MicroPort, the clinical history of the Profemur<sup>®</sup> Plus CoCr Modular Neck PHA0-1254 fractures, and corrosion at the neck-stem junction of the Profemur<sup>®</sup> Plus CoCr Modular Necks, was negligent.

339. The conduct of Defendant Wright Medical Technology, Inc., in not disclosing to surgeons, prior to the sale of the Profemur<sup>®</sup> Product line to MicroPort, the clinical history of the Profemur<sup>®</sup> Plus Modular Neck PHA0-1254 fractures, and corrosion at the neck-stem junction of the Profemur<sup>®</sup> Plus CoCr Modular Necks, was an intentional misrepresentation.

340. The conduct of Defendant Wright Medical Technology, Inc., in not disclosing to surgeons prior to the sale of the Profemur Product line to MicroPort, the clinical history of the Profemur<sup>®</sup> Plus Modular Neck PHA0-1254 fractures, and corrosion at the neck-stem junction of the Profemur<sup>®</sup> Plus CoCr Modular Necks, was fraud.

341. Had Defendant Wright Medical Technology, Inc., accurately and truthfully disclosed to surgeons using its products the clinical history of fractures with the Profemur<sup>®</sup> Plus CoCr Modular Neck PHAC-1254, and neck-stem corrosion with the Profemur<sup>®</sup> Plus CoCr Modular Necks, Plaintiff's surgeon would not have used a Profemur<sup>®</sup> Plus CoCr Modular Neck PHAC-1254 for Plaintiff's March 18, 2015 revision hip surgery.

**COUNT VIII**  
**NEGLIGENT and INTENTIONAL MISREPRESENTATION; FRAUD**  
**by**  
**MICROPORT**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

342. Defendant MicroPort knew that surgeons would rely on the clinical history of the Profemur® Plus CoCr Modular Necks, and in particular the Profemur® Plus CoCr Modular Neck PHAC-1254, in deciding to use, or to continue to use, these products in their patients.

343. Defendant MicroPort Orthopedics, Inc., had a duty to accurately and truthfully disclose to surgeons, including the Plaintiff's surgeon on or before the date of March 18, 2015, the clinical history of fractures with the Profemur® Plus CoCr Modular Neck PHAC-1254, and neck-stem corrosion with the Profemur® Plus CoCr Modular Necks.

344. Defendant MicroPort Orthopedics, Inc., failed to accurately and truthfully disclose to surgeons, including the Plaintiff's surgeon on or before the date of March 18, 2015, the clinical history of fractures with the Profemur® Plus CoCr Modular Neck PHAC-1254, and neck-stem corrosion with the Profemur® Plus CoCr Modular Necks.

345. The conduct of Defendant MicroPort Orthopedics, Inc., in not disclosing to surgeons, including the Plaintiff's surgeon on or before the date of March 18, 2015, the clinical history of fractures with the Profemur® Plus CoCr Modular Neck PHAC-1254, and neck-stem corrosion with the Profemur® Plus CoCr Modular Necks, was negligent.

346. The conduct of Defendant MicroPort Orthopedics, Inc., in not disclosing to surgeons, including the Plaintiff's surgeon on or before the date of March 18, 2015, the clinical history of fractures with the Profemur® Plus CoCr Modular Neck PHAC-1254, and neck-stem corrosion with the Profemur® Plus CoCr Modular Necks, was an intentional misrepresentation.

347. The conduct of Defendant MicroPort Orthopedics, Inc., in not disclosing to surgeons, including the Plaintiff's surgeon on or before the date of March 18, 2015, the clinical history of fractures with the Profemur® Plus CoCr Modular Neck PHAC-1254, and neck-stem corrosion with the Profemur® Plus CoCr Modular Necks, was fraud.

348. The representations as to the clinical history of the Wright Medical titanium Profemur® modular necks that the Defendant Wright Medical Technology, Inc., made to surgeons, as set forth above, were false when made, and Wright Medical knew that they were false.

349. Had Defendant MicroPort Orthopedics, Inc., accurately and truthfully disclosed to the medical community, the clinical history of fractures with the Profemur® Plus CoCr Modular Neck PHAC-1254, and neck-stem corrosion with the Profemur® Plus CoCr Modular Necks, Plaintiff and/or Plaintiff's surgeon would not have used the Profemur® Plus CoCr Modular Neck, PHAC-1254 in the Plaintiff's March 18, 2015 revision surgery.

**COUNT IX**  
**NEGLIGENCE POST-SALE**  
**Wright Medical**  
**Titanium Profemur® Devices**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

350. After Defendant Wright Medical Technology, Inc., began to receive notice that the titanium, Profemur® Modular Necks were fracturing, they did not provide post sale warnings to patients who had these devices implanted that included the following information:

- (a) The modular neck of their hip may suddenly and catastrophically structurally fail, without any warning, by breaking in two, when being used in normal activities of daily living;
- (b) If the modular neck of their hip did suddenly and catastrophically fail, it may cause them to fall, they would most likely not be able to get up, stand on that leg, or walk, and depending on where they were, and what they were doing, at the time of the failure, they could suffer serious injury or death; and,
- (c) These devices were structurally failing by fractures of the modular necks in patients of many different weights and levels of activity.

351. After Defendant Wright Medical Technology, Inc., received notice that the Profemur® Modular Necks were fracturing, they did not request surgeons who implanted these devices to provide patients with these devices, at Defendants' expense, post-sale warnings that included the following information:

- (a) The modular neck of their artificial hip may suddenly and catastrophically structurally fail, without any warning, by breaking in two, when being used in normal activities of daily living;
- (b) If the modular neck of their hip did suddenly and catastrophically structurally fail, it may cause them to fall, they would most likely not be able to get up, stand on that leg, or walk, and depending on where they were, and what they were doing, at the time of the failure, they could suffer serious injury or death;
- (c) These devices were structurally failing by fractures of the modular necks in patients of many different weights and levels of activity;
- (d) These devices were structurally failing by fractures of the modular necks when being used by patients for work, recreation, and lifestyles that Defendants Wright Medical and MicroPort had marketed and advertised these devices as being appropriate for; and,
- (e) The titanium Profemur® Modular Neck, PHA0-1254, has the highest number, and the highest rate, of premature failure by fracture at the neck stem junction.

352. Had defendant provided such warnings to the Plaintiff, he most probably would not have elected to have revision surgery where another long Profemur® Modular Neck with the same version [angles] would be implanted.

353. The conduct of the Defendants Wright Medical Technology, Inc., and MicroPort Orthopedics, Inc., to provide post-sale warnings, as set forth above, was negligent.

354. The conduct of the Defendants Wright Medical Technology, Inc., and MicroPort Orthopedics, Inc., as set forth above, directly and proximately caused injuries and damages to the Plaintiff.

**COUNT X**  
**NEGLIGENCE POST-SALE**  
**Wright Medical and MicroPort**  
**Profemur® Plus CoCr Modular Necks**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

355. After Defendants Wright Medical Technology, Inc., and MicroPort Orthopedics, Inc., began to receive notice that the Profemur® Plus CoCr Modular Necks, PHAC-1254, were corroding and fracturing, just as had hundreds of the Wright Medical titanium Profemur Modular necks, they did not provide post sale warnings to patients who had these devices implanted that included the following information:

- (d) The modular neck of their hip may suddenly and catastrophically structurally fail, without any warning, by breaking in two, when being used in normal activities of daily living;
- (e) If the modular neck of their hip did suddenly and catastrophically fail, it may cause them to fall, they would most likely not be able to get up, stand on that leg, or walk, and depending on where they were, and what they were doing, at the time of the failure, they could suffer serious injury or death; and,
- (f) These devices were structurally failing by fractures of the modular necks in patients of many different weights and levels of activity.

356. After Defendants Wright Medical Technology, Inc., and MicroPort Orthopedics, Inc., received notice that the Profemur® Plus CoCr Modular Necks, PHAC-1254, was fracturing, they did not request surgeons who implanted these devices to provide patients with these devices, at Defendants' expense, post-sale warnings that included the following information:

- (f) These Profemur® Plus CoCr Modular Neck, PHAC-1254, has been recalled from the market due to a risk of fracture;

- (g) The modular neck of their artificial hip may suddenly and catastrophically structurally fail, without any warning, by breaking in two, when being used in normal activities of daily living;
- (h) If the modular neck of their hip did suddenly and catastrophically structurally fail, it may cause them to fall, they would most likely not be able to get up, stand on that leg, or walk, and depending on where they were, and what they were doing, at the time of the failure, they could suffer serious injury or death;
- (i) These devices were structurally failing by fractures of the modular necks in patients of many different weights and levels of activity; and,
- (j) These devices were structurally failing by fractures of the modular necks when being used by patients for work, recreation, and lifestyles that Defendants Wright Medical and MicroPort had marketed and advertised these devices as being appropriate for.

357. The conduct of the Defendants Wright Medical Technology, Inc., and MicroPort Orthopedics, Inc., to provide post-sale warnings, as set forth above, was negligent.

358. The conduct of the Defendants Wright Medical Technology, Inc., and MicroPort Orthopedics, Inc., as set forth above, directly and proximately caused injuries and damages to the Plaintiff.

**COUNT XI**  
**CONDUCT MERITING PUNITIVE DAMAGES**  
**Wright Medical and MicroPort**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

359. The acts and omissions of the Defendant Wright Medical Technology, Inc., as set forth in this Complaint, constitute intentional, fraudulent, malicious and/or reckless conduct. Accordingly, Plaintiff is entitled to an award of punitive damages against Defendant Wright Medical Technology, Inc.

360. The acts and omissions of the Defendant Wright Medical Technology, Inc., as set forth in this Complaint, constitute intentional, fraudulent, malicious and/or reckless conduct.

Accordingly, Plaintiff is entitled to an award of punitive damages against Defendant MicroPort Orthopedics, Inc.

### **DAMAGES**

Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

361. As a direct and proximate result of the acts and omissions of the Defendants alleged herein, Plaintiff was injured and damaged. The injuries and damages for which Plaintiff seeks compensation from the Defendants include, but are not limited to:

- a. physical pain and suffering of a past, present and future nature;
- b. emotional pain and suffering of a past, present and future nature;
- c. permanent impairment and scarring;
- d. medical bills and expenses of a past, present and future nature;
- e. loss of earnings;
- f. loss of earning capacity;
- g. loss of enjoyment of life;
- h. punitive damages;
- i. pre-judgment and post-judgment interest;
- j. statutory and discretionary costs; and,
- k. all such further relief, both general and specific, to which they may be entitled to under the premises.

### **PRAYERS FOR RELIEF**

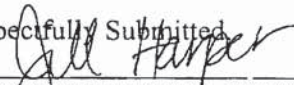
WHEREFORE, Plaintiff prays that judgment be entered in his favor, and that he be awarded compensatory damages from the Defendant Wright Medical Technology, Inc., Defendant

MicroPort Orthopedics, Inc., and Defendant PellMed, LLC, jointly and severally, for his personal injuries and damages, and for an award of punitive damages, severally, against Defendant Wright Medical Technology, Inc., Defendant MicroPort Orthopedics, Inc., and for all such further relief, both general and specific, to which Plaintiff may be entitled under the premises.

**JURY DEMAND**

Plaintiff requests a jury trial for all issues so triable.

**WHEREFORE**, Plaintiff, Curtis L. Mahnken, prays that the Court enter judgment in his favor and against Defendants in an amount commensurate with his damages including compensation, consequential, and exemplary damages, and for any further and additional relief as this Court deems just and proper.

Respectfully Submitted  
By:   
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*/s/ George McLaughlin*

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